Technical File

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-4-06

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Device description

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1. Company introduction

Zhejiang Haipai Pharmaceutical Co., Ltd (hereinafter referred to as Haipai), a company especially focusing on medical supplies & trays design, development and manufacturing in China was established in 2015 with a group of Senior personnel with professional background.

Haipai established strict quality management system based on YY / T 0287, ISO 13485 and FDA 21 CFR Part 820, with high standards of design and production of medical equipment box. Adhering to the "safe and reliable, the pursuit of excellence" quality policy, Company is committed to being a fast, responsive, and reliable provider of case and tray systems to orthopedic OEMs. with scientific management, excellent equipment, first-class talent and high quality services.

Manufacturer:
Name:Zhejiang Haipai Pharmaceutical Co., Ltd
Add:Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China
Tel: 86-0577-89619889
E-mail: 28408644@qq.com

Authorized representative of European Union:
Name: Luxus Lebenswelt GmbH
Add: Kochstr. 1, 47877, Willich, Germany
DIMDI Code: DE/0000047791
Tax Number: DE305829099
Contact Person: Lin Sun
Tel/Fax: 0049-1715605732
E-mail: Info.m@luxuslw.de

Device description
Device name: Disposable Medical Mask
Model: 17.5*9.5cm
This product consists of a mask, a nose clip and a mask band. The mask is made of non-woven fabric. The nose clip is made of a plastic material. The mask band is made of elastic material. Disposable, non-sterile.

1. Indication for use

Intended user: For clinical staff to wear during non-invasive operation. It covers the mouth, nose and mandible of the user, providing a certain physical barrier to prevent the direct penetration of pathogens, microorganisms, particles, etc.

2. Contraindications

None

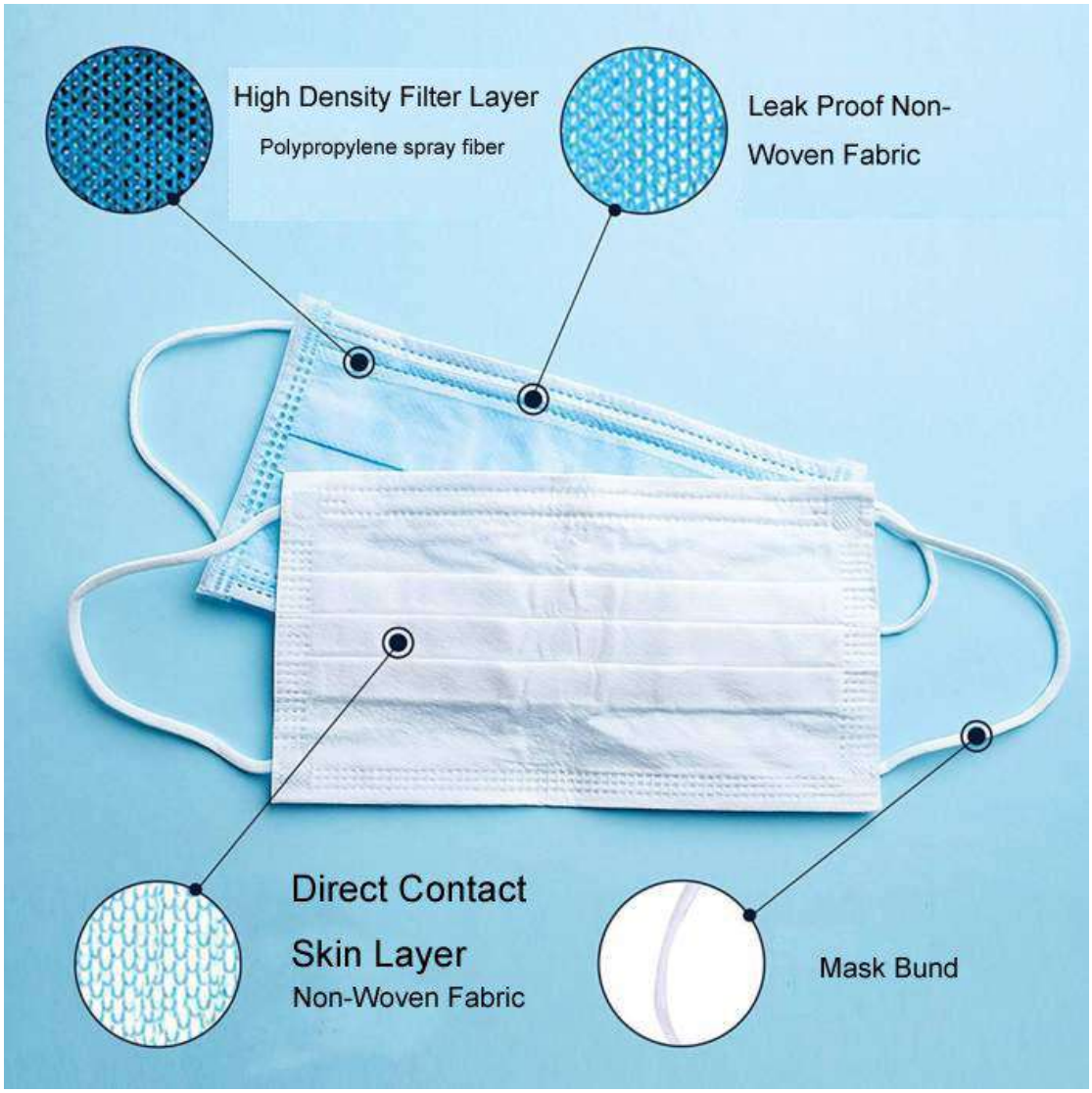
3. Principle

Disposable Medical Mask consists of mask, nose clip and mask belt. The mask is made of three layers of non-woven fabric, the outer layer is spun bond non-woven fabric, the main function is to prevent splashes such as saliva, the middle layer is melt blown non-woven fabric, the main function is to filter bacteria and viruses, the inner layer is spun bond non-woven fabric, the main function is to absorb moisture and increase comfort, the nose clip is made of plastic materials, the main function is to make the mask fit the face, and prevent bacteria and viruses from flowing from the mouth The gap between the mask and the face enters the mouth or nose.

4. Normal conditions of use:

Store the product at room temperature. Avoid direct sunlight. Keep the storage environment clean, dry and well ventilated

5. Structure



6. Device performance

Disposable Medical Mask		
performance	Bacterial filtration efficiency （BFE）	Not less than 95%
	Ventilation resistance	Not more than 40 Pa / cm2
	Breaking strength at the connection point of each mask band to the mask body	Not less than 10N
	Microbial	≤30cfu/g
Product Specifications	Structure and size	175mm long 95mm wide Allowable error ± 5%
	Nose clip	length is not less than 8.0cm

7. Accessories

None

8. Shelf life

24 Months

9. Classification

According to the intended use of the product and Annex VIII of Medical Device Directive 93/42/EEC:
Product name: Disposable Medical Mask
Classification: Class I, Rule 1

10. Conformity assessment

The Disposable Medical Mask has been manufactured under a quality management system according to Chapters I and III of Annex IX of Medical Device Directive 93/42/EEC and the product apply CE certification following the instruction from Chapters I and III of Annex IX.

11. Notified body

None

12. Statement

We declare the device do not contain any raw materials produced from or substances derived of animal origin and free from TSE (Transmissible Spongiform Emcephalopathy), medicinal substances, human blood derivatives and phthalates.

13. Previous generation and device history

This product is the first generation.
Disposable Medical Mask products and related technologies have been in the market for a long time, and the principles and performance of the products have remained basically the same. Our company's products have been placed into the EU market based on MDR regulatory.

14. EC-Rep Agreement(attachment)

Annex1-EC-Rep. Agreement

EU Representative Agreement

Document Number: JH-ERA-20393V00

This agreement will be valid for1 year from 2020.3.20to 2021.3.19. Part A could choose to renew the agreement by then, otherwise this agreement will be terminated automatically.此合同有效期为1年，自2020年3月20日至2021年3月19日。到期后由甲方选择续约或合同自动失效。

Part A (甲方)	
Name(名称):	Zhejiang Haipai Pharmaceutical Co., Ltd
Add(地址):	Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China
Zip Code(邮编):	325000
Contact Person(联系人):	Liu Hui
Tel/Fax(联系电话/传真):	0577-89619889
E-mail(邮箱):	28408644@qq.com
Party B (乙方)	
Name(名称):	Luxus Lebenswelt GmbH
Add(地址):	Kochstr. 1, 47877, Willich, Germany
DIMDI Code:	DE/0000047791
Tax Number:	DE305829099
Contact Person:	Lin Sun
Tel/Fax:	0049-1715605732
E-mail:	Info.m@luxuslw.de
Competent authority(主管当局信息)	
Name	Bezirksregierung Düsseldorf, Dezernat 24
Federal state	Nordrhein-Westfalen
City	Düsseldorf
Postal code	40474
Street, house no.	Cecilienallee 2
Phone/Fax	+49-211-4750 / +49-211-4752671
E-mail	dez24.mpg@brd.nrw.de

Party A hereby appoints Party B as the authorized European Representative for their Medical Device with CE mark, Party B accepts the appointment to be the authorized European Representative for Party A in the market of European Union（E.U）, EEA and Switzerland, Turkey, Both parties enter this agreement as follow, the appointed product categories set out in below form:
甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命,为甲方在欧盟、EEA、瑞士、和土耳其市场的CE医疗产品授权代表,双方签署下列协议,委托的产品类别见下表：

No.	Product Name/产品名称	Models/型号	Classification/分类
1	**Disposable medical mask**	**17.5*9.5cm**	Class I

I. Obligations and Liabilities of Party A

甲方职责和义务

1. Party A assures to provide the updated technical files of each product category with CE mark to Party B. If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/ vision), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files as following:
甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档。如果甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此而引起的所有后果。甲方必需提交电子文件，文件可以是PDF/WORD/JPG/格式的任何一种。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文档内容的要求如下：
   (i) Declaration of conformity, 符合性声明
   (ii) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed), 标签、包装、说明书副本（所有上市国家要求的语言的版本）
   (iii) Notified Body certification (where relevant), 公告机构证书（适用时）
   (iv) Post market surveillance process and data, vigilance reports and complaints, processes and data, 上市后监督过程和数据、警戒报告以及投诉、处理和数据
   (v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State, 与欧盟成员国上市监督调查有关的技术文件
   (vi) Relevant clinical data / notification, 相关的临床数据/通知
   (vii) Details of any distributors / suppliers putting the CE marked devices on the market, 经销甲方CE标志医疗器械的经销商/供方细节
   (viii) Incident reports and corrective actions taken. 事故报告及采取的纠正措施
2. Before each product listed in this agreement is placed into the EU market, Party A must notify Party B and provide Party B with product labeling updated and details of any distributors /suppliers in EU, otherwise this agreement will be terminated automatically, Party A should take on any aftereffect by itself.
本协议所涉及的每个产品在投放到欧盟市场之前，甲方必须通报给乙方，并且应向乙方提供最新的产品标签文件和欧盟经销商/供方的信息，否则本协议自动失效，甲方承担由此而引起的所有后果。
3. If there are any changes of products and update of technical file, Party A shall notify Party B with change notification in electronic copy as soon as possible. Party A shall send relevant information to Party B's email listed as below within one week upon changing information: info.m@luxuslw.de.
产品如有改变，技术文件如有更新，甲方需要在更新信息产生后一周之内以电子邮件的形式将相关信息发送到乙方以下电子邮箱：info.m@luxuslw.de。
4. If any accident/near accident of products(including any serious adverse event during clinical investigation in premarket stage)(see clause A1.5 e of "Guideline for Authorized Representatives(MEDDEV 2.5/10)(January 2012)") happens within boundary of E.U.,EEA and Switzerland, Turkey, Party A shall help Party B to investigate the reason in time, and complete the initial report together with Party B. Party A shall present the investigation result and final report to

Party B according to MDD 93/42/EEC (MDD products) ,IVDD 98/79/EC (IVDD products) and the Guidance of vigilance system. If the accident of the product happens out of E.U., Party A shall notify Party B as soon as possible, and Part B should make decision whether to report to competent authority or not.

If the above mentioned accident/near accident of products was known by Party A at first, Party A must send notification to the email of Party B as stipulated in Article 2 hereof in two calendar days and provide the complete report of the investigation, analysis and disposal result of the accident/near accident to Party B by E-mail or other effective means in writing within one week after relevant accident happened.

如果产品在欧盟境内及 EEA 和瑞士、土耳其之发生事故或者准事故（包括在上市前的临床调查阶段发生的严重不良事故（详见"Guideline for Authorized Representatives（MEDDEV 2.5/10）(2012 年 1 月)"），甲方应及时配合乙方调查原因，并同乙方一起负责完成初始报告。甲方应在《欧洲共同体理事会法令》按 MDD 93/42/EEC （MDD 产品）或 IVDD 98/79/EC （IVDD 产品）和《警戒系统指南》规定的时间内向乙方报告调查结果和最终报告。如带 CE 标志的产品，其事故、准事故发生在欧盟境外，甲方应尽快告知乙方，并由乙方决定是否向主管当局报告。

如果上述事故、准事故是通过甲方渠道先期获得的，甲方须立即在两个自然日内以电子邮件形式发送至上述第2条中的电子邮箱中；并需要对事故、准事故的调查、分析和处理结果的报告，用电子邮件或书面方式在相关事件产生后一周内通知乙方。

5. Party A shall be responsible for any business dispute related to their product problems, such as medical accidents or claims for compensation concerning quality that arise after sale. Party B shall assist Party A to handle the dispute in accordance with the authorization of Party A. All the expenses occurred outside the china mainland during Party B's handling of the accident shall be borne by Party A. Party A should pay all of the cost of the traffic and other allowance for PART B's employee or advisor in the china mainland for the need of investigation, analysis and disposal of the accident. Party B is entitled to require Party A to pay in advance. Before Party B receives such payment Party B is entitled to refuse to pay on behalf of Party A or take relevant measures.

甲方应对销售后发生的与其产品相关的医疗事故或质量索赔等业务纠纷负责。乙方根据甲方的授权，协助甲方联络处理。在事故处理中，乙方需要在境外支付的相关费用，须甲方确认后由甲方承担。如果由于调查、取证质量投诉、事故和索赔的需要，乙方雇员或顾问在赴中国内地企业工作的食宿、交通等实际支出的费用，由甲方承担，乙方可以要求甲方支付相应的预付款，在该预付款到账到达乙方指定账户之前，乙方有权利拒绝代为支付或者采取相关措施。

6. Party A should keep the complete sales list of all of the products exporting to any area of E.U, EEA and Switzerland (including the OEM products) by electrical documents in English at least 5 years, in order to be provided by Party B for the using to be transferred or inspected to the relevant competent authorities of E.U., EEA and Switzerland, Turkey Party A assures the accuracy and the validity of the data.

甲方出口欧盟地区及EEA和瑞士、土耳其之所有产品的销售清单（包括OEM的销售清单），在产品停产后至少五年期间，必须用英文文字、电子文档形式保留完整无缺，以备乙方随时用于欧盟及EEA和瑞士之官方的调用、检查。甲方要对提供的数据其准确性、真实性负责。

7. Party A must notice Party B the complaint record and the result of disposal on the accident of products immediately, and Party A should save, transfer, check-up any of the record according to the 5th article on the above.

甲方针对客户/用户的事故或者准事故的投诉、抱怨记录和处理结果，除了应该及时通知乙方以外，所有记录的保存、调用、检查，按照上述第"5"条条款办理。

8. Party A should appoint one persons as the primacy linkman who connect with Party B and deal

with the normal daily grind according to this agreement. Information of both Parties' linkman should be written in Page one. The information delivered to the primacy linkman who connect with Party A by Party B shall be deemed as delivery to Party A and the instruction provided by the primacy linkman who connect with Party A shall be deemed as the instruction from Party A.
甲方需指定一人，作为甲、乙双方的第一联络人，主要职责是与乙方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的第一页。乙方送达给甲方联络人的信息视作送达给甲方，甲方联络人给出的相关指示视作甲方给出的指示。

9. Party A shall fully realize the risk of selling its products to EU, EEA and Swiss, Turkey market without product registration to relevant competent authority of E.C. If it caused by Party A, such as delay, admittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU, EEA, and Swiss, Turkey market will be prohibited.
甲方需要充分认识到本企业产品由于迟缓、延误、疏漏或者隐瞒而造成产品没有登记备案就销售欧盟市场及 EEA 和瑞士、土耳其之必定带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入欧盟及 EEA 和瑞士之市场的，甲方将承担罚款、警告，甚至直至吊销 CE 产品证书和禁止产品进入欧盟市场及 EEA 和瑞士、土耳其之的后果。
10. Party A shall notify of the intention to Party B to carry out a clinical investigation for MDD or AIMDD, and the intention to carry out a performance evaluation for IVDD performed in EU, EEA and Swiss,Turkey.
甲方应通知乙方在欧盟、EEA 和瑞士及土耳其对医疗器械或者有源植入性医疗器械进行临床试验的计划，以及对体外诊断试剂进行性能评估的计划。
11. Party B is released by Party A of any liability relating to the medical devices manufactured by Party A.
甲方承诺，乙方不对甲方生产的医疗器械的索赔承担任何责任
12. Party A will be fully responsible for the performance of its products and will hold Party B harmless against any liability claim arising from the use of the products manufactured by Party A.
甲方为其产品性能承担全部责任，并将确保乙方不会因为甲方生产的产品在使用过程中产生的任何责任索赔而承担损失。
13. Any liabilities for damage to any third party attributed to service stipulated herein provided by Party B, Party A shall bear all liabilities for damage and undertake to exempt any responsibilities of Party B to any third party. If it is required for Party B to employ any expert and counsel, especially to employ legal counsel to provide consultation and legal agency, Party A shall bear all relevant fees caused by the employment and pay such fees in advance upon request of Party B.
如果乙方因提供本协议规定的服务而产生对第三方的赔偿责任，甲方应当全权承担相关赔偿责任，并免除乙方对外的责任。如果乙方由此需要聘请专家和顾问，特别法律顾问提供咨询和法务代理，甲方应承担乙方因此而产生的相关合同费用，乙方有权要求甲方预付相关费用。

II. Obligations and Liabilities of Party B
乙方的职责和义务

1. About the register for Party A's products with CE mark to relevant competent authority of E.C., Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Germany) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly.
If it needs any expenditure by the competent authority, only after getting Party A's approval, then

Party A can take on the payment. If Party A's products register fails by Party B's reason, according to Germany/EU relevant laws Party B will be given a warning, penalty and even the qualification of the European Representative will be revoked.
如果甲方已加贴 CE 标志的产品按欧盟相关规定必须需要办理 CE 产品欧盟登记备案的，需先由甲方提出申请，并提供所有符合规定的文件并填写申请表格，经乙方初步认可后，由乙方负责在 7 个工作日完成初审，5 个工作日内提交乙方所在国德国主管当局审核申请登记备案的文件。但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请，不在此时间规定之列。
德国主管机构审核上述登记备案如需要收取相关费用的，需经甲方同意方可由乙方代为支付。如果由于是乙方的原因，甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的，根据德国/欧盟有关法律法规，乙方将受到警告、罚款、吊销担任欧盟代表资格的处罚。

2. Party B shall reserve technical files of each category of party A's products with CE mark. The technical files shall be reserved for at least ten years after manufacturing of the last batch of products. Once competent authority needs the technical files (including new edition of the technical files which had already registered) of each category of part A's products with CE mark. Party B should send them to competent authority within ten workdays.
乙方应保留甲方每一大类获得 CE 标志产品的技术文档，该文档至少保存至最后一批产品出厂后十年。一旦欧盟主管当局需要获得 CE 标识产品的技术文件（含已备案的技术文件的新版本），乙方负责在 10 个工作日内递交欧盟主管当局。
3. Upon receiving the CE technique files, Party B shall gave a electronic receipt to Party A within 3 working days. It's the evidence that Party B have received all the required files. Party B would not be responsible for the file content. All the documents, such as sales list and complain records are deemed confidential information; Party B have the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.
乙方收到甲方提供的CE技术文档等文件的3个工作日内，向甲方出具电子"回执"；该"回执"仅证明乙方收到甲方的文件，而不对文件的内容负责。乙方对甲方提供的销售清单、投诉记录等文件，负责递交欧盟相关机构审阅并负有保管、保密的责任。
4. Party B shall notify any information about the products with CE mark within the Boundary of E.C., including any claims of customers and the competition company that produce the same CE marked products, to Party A.
乙方应将有关 CE 产品在欧盟境内的任何消息(包括客户投诉和同类竞争企业)及时通知甲方。
5. If any serious accident of products happen within boundary of E.C., Party B shall notify Party A within two calendar days of complaint or feedback on Party A's products and assist Party A to execute vigilance system of medical device products, and also make the initial report together with Party A. Party B shall then present the initial report, investigation results and the final report to competent authority of country in which the accidents happen.
如果带有 CE 标志的产品在欧盟境内发生严重事故，乙方应在收到有关甲方产品的投诉或反馈信息两个自然日内通知甲方，并在甲方的协助之下调查原因，同甲方一起负责完成初始报告。乙方负责把完成的初始报告、调查结果和最终报告向事故发生国主管当局提供。
6. Party B shall appoint one persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in first page of this contract.
乙方需指定一人，作为甲、乙双方的第一联络人，主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的第一页。

7. Party B shall assist Party A to comprehending the condition of the same products within boundary of E.U, and send the related information to Party A in time.
乙方协助甲方了解欧盟市场同类产品的情况，并及时反馈给甲方。
8. Party B shall keep all technical files and information of Party A's in confidentiality.
乙方应对甲方技术文档和资料保密。

III. SERVICE FEE 服务费用

Party A shall pay the service fees to Party B separately according to the agreement for the relevant service provided by Party B.
就乙方提供本协议规定的相关服务，应当按照单独约定支付乙方服务费用。
Provided that Party A requires Party B to provide the service beyond scope stipulated herein, both parties shall agree relevant fees separately in writing.
如果甲方需要乙方提供超出本协议规定之外的服务，甲乙双方应当对此另行书约定相关费用。

IV. Others

1. Written Form Clause 书面形式
Amendments to this Contract shall only be valid when given in writing. The requirement of form may only be waived in writing. Verbal collateral agreements or modifications are not valid.
本意向协议的任何更改与补充均需以书面形式进行。这一规定同样适用于本条款（关于书面形式）的修改。口头协议和口头修改无效。
2. Contract Language 合同语言
This agreement exists in English and Chinese language. The Chinese version is an exact duplicate of the English version.
本协议为中文和英文的对照版本，中文版本和英文版本内容完全一样。
3. Severability clause 可分割性条款
If any provision of this agreement or a provision incorporated herein at a later date is or shall become invalid in whole or in part, or if this agreement or any modification thereof is found to have a gap, this shall not affect the validity of the remaining provisions. It is, however, the express intention of the parties to maintain the validity of the other provisions of the agreement under all circumstances. In place of any invalid provision or to fill a gap, a valid and enforceable provision shall be agreed which most closely corresponds legally and economically to that which the parties intended or would have intended within the meaning and purpose of the agreement and any later modifications, if they had considered this issue when concluding the agreements. If the invalidity of any provision is due to a measure of performance or time (time-limit or date) stated therein, a measure of performance which most closely corresponds to the original measure in a legally admissible way must be agreed for this provision.
如若本协议中的条款或者其补充于现在或者将来无效，其他部分不受其影响，该规定同样也适用于协议内容缺失的情形。但协议双方明确表示，上述可分割性条款是为了确实保证合同其它部分不因合同部分无效而整体无效受到影响。就无效条款和缺失部分，协议双方应当在法律允许的范围内本着最接近原有合同目的，最能达到共同预期为标准，达成有效的补充规定，以替代该无效条款或者填补协议内容的缺失。

This agreement is subject to the requirement specified in the <EU 93/42/EEC Directive 1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the < MEDDEV 2.12-1 REV.8 January 2013>. Should there be any conflicts between this agreement and <EU 93/42/EEC Directive

1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the < MEDDEV 2.12-1 REV.8 January 2013> shall be followed as standards. If the regulation above update or change, Party A and Party B should actively negotiate and communicate to ensure that the requirements of the new regulation are met.

本协议受《欧共体关于医疗器械的 93/42/EEC 指令》，《欧共体关于医疗器械的2007/47/EEC 指令》，《欧共体关于体外诊断医疗器械的98/79/EC 指令》和《医疗器械警戒体系指南》约束。如本协议条款与《指令》或《指南》冲突，以《指令》和《指南》为准。如上述法规发生更新或变更，甲乙双方应积极协商和沟通，确保持续满足新法规的要求。

During the implementation of the agreement, this agreement will be terminated automatically when:

在协议执行期间内，下列日期为本协议的自动终止日期：

(a) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.

(When the above mentioned things happen, Party A is obligated to accomplish the following processes to avoid the further consequences:

甲方的 CE 证书因事故被发证机构暂时吊销/关闭/收回的。

(以上事实一旦发生，甲方需主动配合乙方做好以下善后工作，否则将承担由于不作为或者作为不当而产生的所有责任：

- Brief statement in written about the reasons why CE Certificate being withdrawn, being closed or being recalled by the notified body. 书面简要说明证书被吊销/关闭/收回的原因。包括更换公告机构的理由。
- Written statement of non-sales if there are no products under the withdrawn, closed or recalled CE Certificate exporting to EU, EEA and Swiss, Turkey market, or if there are products exporting, a written statement of sales would be required with the sales lists, risk assessments and the measures and timetable to cover the risk.)

  书面确认被取消的CE证书所有所列产品是否已经有出口欧盟市场以及EEA和瑞士、土耳其之市场。如果没有，请出具书面声明，如果有，请附上出口销售清单，同时请书面评估由此可能产生的风险并陈述甲方解决问题的措施和时间表。)

(b) Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or before using CE mark for "self declaration" products. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.

甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效。在本失效之日起的60天内，为了能够方便甲方聘请新的欧盟代表及更改CE证书等相关工作，乙方可以代为继续行使欧盟代表日常事务。乙方应该将与甲方失效的协议信息及时报公告机构备案。

(c) Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.

甲方没有按协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

No other rights or obligations are applied to Party A or Party B other than specified in this agreement.

除本协议外，甲、乙双方不赋予其他权利和义务。

Luxus Medical

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

PART A:

Signature(签字):
Company Stamp(公章):
Date(日期):

PART B: **Luxus Lebenswelt GmbH**

For and on behalf of
LUXUS LEBENSWELT GMBH
Kochstr. 1, 47877 Willich, Germany

Signature(签字):
Company Stamp(公章):
Date(日期):

Authorized Signature:
Simon Qian
Only used for EU Representative agreements

Device Labelling

According to Council Directive 93/42/EEC

File No.: TCF-ZJHP-001/02-01

Version: A/0

Product: Disposable Face Mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-3-16

1. Label

Haipai Medicine

Zhejiang Haipai Pharmaceutical Co., Ltd

Disposable Medical Mask

CE

LOT	2020-03-15

QUANTITY	50pcs/box 40boxes/case

PACK	Plastic
OUTER CASE	carton

Do not use if units package is opened or damaged.

Size : 17.5*9.5cm

2020.03 2022.03

NON STERILE

EC REP

Zhejiang Haipai Pharmaceutical Co., Ltd
Address: Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany
0049-1715605732

2. Package information

This product adopts three-level packaging method of inner layer, middle layer and outer layer. The inner layer is made of polyethylene (PE) transparent packaging bag, the middle layer is made of ordinary carton, and the outer layer is made of corrugated box.The packing specifications are 10 pieces / package for the inner layer, 5 packages / box for the middle layer and 40 boxes / box for the outer layer.

3. Packaging Design

The label should bear the following particulars:

3.1 The name, address and contact information of the manufacturer;

3.1.1 Symbol

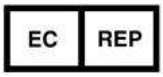
3.1.2 This symbol shall be accompanied by the name and the address of the manufacturer, adjacent to the symbol;

3.1.3 Example of use

 Name Address

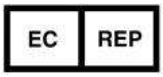
3.2 The name and address of its authorized Europe representative;

3.2.1 Symbol



3.2.2 This symbol shall be accompanied by the name and the address of the authorised representative in the European Community, adjacent to the symbol;

3.2.3 Example of use



Name Address

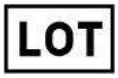
3.3 An indication that the product is for single use with wording (DO NOT RE-USE)

3.3.1 Symbol

3.3.2 Synonyms for "Do not reuse" are "single use", "Use only once".

3.4 Batch code

3.4.1 Symbol



3.4.2 This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol;

3.4.3 The sizes of symbols and batch code are not specified.

3.4.4 Example of use

ABC123

3.5 Symbol of instruction for use of product and its particulars

3.5.1 Symbol

 Consult instructions for use

3.5.2 The shape of the bar or triangle is not specified.

3.5.3 Below the symbol particulars to be cautioned by the user are indicated.

3.6 Label shall bear a CE mark.

3.6.1 Symbol

CE marking shall be in accordance with REGUL ATION (EU) 2017/745.

3.6.2 CE marking shall be prominent, visible, legible, and indelible.

3.7 Symbol for “NON STERILE”

3.8 Symbol for “USE BY”

3.8.1 Symbol

3.8.2 This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown. The date shall be expressed as given in ISO 8601, as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol.

3.8.3 Example of use

 2019-06-28

It means that the device should not be used after June 28th, 2019.

3.9 Symbol for “DO NOT USE IF PACKAGE IS DAMAGED”

3.9.1 Symbol

3.9.2 Synonym for "Do not use if package is damaged" is "Do not use if the product sterilization barrier or its packaging is compromised".

3.10 Symbol for fear of sun and fear of rain

3.10.1 Symbol

3.10.2 Packaging on the fear of rain, fear of sun to identify the logo, marked on both sides of the packaging.

4. Language

The language written in the label shall meet the language requirements of EU member states, and its correctness shall be guaranteed.

5. Special Requirements

For label upon which the customer has some special requirements, the design should not only meet the special requirements, but also satisfy the above requirement.

6. Instruction for use

Please refer to document “CF-ZJHP-001/02-02 Instruction for use”.

Disposable Medical Mask
Product manual

[Product name]

Disposable Medical Mask

[Product model / specification]

17.5cm*9.5cm

[Scope of application]

For the health care of the wearer in the Zengtong medical environment without the risk of body fluids and splashes. For special protection when not performing surgery.

[Product structure and composition]

Disposable Medical Mask consists of nonwoven fabric layer and mask belt.The nonwovens layer is composed of nonwovens and melt blown fabrics by folding,The outer layer is Nonwovens,The interlayer is melt blown cloth.

[Main performance of the product]

1.Filtration efficiency

1.1 Bacterial filtration efficiency（BFE）

The bacterial filtration efficiency of mask shall not be less than 95%.

1.2 Particle filtration efficiency（PFE）

The filtering efficiency of mask for non oil particles shall not be less than 30%.

2. Microbial index

Mask should be sterile.

[Method of use]

1. The method of wearing disposable masks is relatively simple, but also pay attention to air tightness, do not touch the surface of the mask after getting it;

2. Disposable masks are divided into inside and outside. The light-colored surface has the function of absorbing and discarding dark moisture. When using it, it should be

close to the mouth and nose, with the dark-side facing outward

3. When using, unfold the mask. When unfolding, adjust it according to your face shape, and completely cover the nose, mouth and jaw;

4. The fourth step is to press the upper nose clip. You can use both hands to press the hard side on the upper side to fit the nose wings.

5. After pressing, make the mask completely fit with your face. At this time, you can feel if there is any air leak during breathing

[Registration and warning]

1、This product is a one-time use product and must not be reused; the inner packaging of the product should not be used if it is damaged, damp or moldy.

2、 After the product is used, it should be processed according to the requirements of relevant departments.

[Product storage and transportation]

1、This product should be protected from moisture, fire and pollution during transportation, and should not be exposed to toxic or harmful items.

2、 This product should be stored in a dry and clean room, and the room should be ventilated and ventilated.

[Production date and service life]

Production date: see label

Expiry date: see label

Product shelf life: 2 years

[Essential information]

Name of registrant / manufacturer:

Zhejiang Haipai Pharmaceutical Co., Ltd

Address of registrant / manufacturer:

Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China

Production address:

Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China

Contact information of registrant / manufacturer:

After-sales service unit:

Zhejiang Haipai Pharmaceutical Co., Ltd

+86-0577-89619889

[Registration information]

Number of medical device registration certificate / product technical requirements:

Production license number:

[Date of preparation or revision]

[Explanation of medical device label]

	Avoid rain		Do not reuse
	Be careful		Do not use if package is damaged
	Refer to instructions		Non Sterile

Design and manufacturing information

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001/03

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-3-16

1. Product design procedure

1.1 Design input

No.	Standards	
1	EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
3	EN 1041:2008+A1: 2013	Information supplied by the manufacturer of medical devices
4	EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices
5	EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
6	EN ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
7	EN ISO 10993-5-2009	Biological evaluation of medical devices - Part 5: Cytotoxicity test - In vitro method
8	EN ISO 10993-10:2013	Biological Evaluation of Medical Device-Part 10: stimulation and allergic reaction
9	BS EN 14683:2019	Medical face masks-Requirements and test methods

1.2 Design output

- Raw material information

Name of raw material	Performance	technical specification
Outer waterproof non-woven fabric	Element	100%PP
	Outer	Soft, no color change, no stains, no holes, even cloth
	Width （cm）	17.5±0.2
	Weight (g/m2）	22±10%
	Longitudinal fracture strength（N）	≥ 35
	cross-breaking strength（N）	≥ 35
	Longitudinal elongation at break（%）	≥ 40%
	Transverse elongation at break（%）	≥ 40%
Meltblown cloth	Outer	There must be no damage, stains or color difference
	Width （cm）	17.5±0.2
	Weight (g/m2)	22±2
	Whiteness	≥80%

	Flow (L/min)	32
	Resistance (mmH2O)	≤ 2.0
	transmission rate(%)	≤ 18
	Bacterial filtration efficiency-BFE (%)	≥ 95
Inner layer ordinary non-woven fabric	Element	100%PP
	Outer	Soft, no color change, no stains, no holes, even cloth
	Width （cm）	17.5±0.2
	Whiteness	≥80%
	Weight （g/m2）	22±10%
	Longitudinal fracture strength（N）	≥ 35
	cross-breaking strength（N）	≥ 35
	Longitudinal elongation at break（%）	≥ 40%
	Transverse elongation at break（%）	≥ 40%
Ear bands	Outer	No black impurities or stains
	DE %	≥550
	SS300variable coefficient	≤10.0
	breaking strength g/d	≥1.2
	Size d	40±1
	il length %	2-5
	boiling water shrinkage%	10-14
	Elastic recovery at 300% elongation%	≥95
bridge of nose	Outer	No stains, no foreign matter, flat, no sharp edges
	Weight (g/m)	4.0 g/m±0.2 g/m
	Thickness（mm）	0.50±0.02 mm
	Widthmm	2.7-3.1 mm

Product manufacturing specifications, such as operating specifications for parts, sub-packaging, raw materials, and packaging

Fully automatic face mask machine is used to realize the whole process from feeding to finished product. Including automatic material delivery, automatic delivery, cutting of the nose bridge strip, mask edge welding, folding, ultrasonic fusion, molding, cutting and other full process automation, complete the entire production process from the raw material of the coil to the finished mask.

The earband mask machine uses ultrasonic welding. When the mask is moved to the processing position, ultrasonic waves are automatically generated, forming a micro-amplitude high-frequency vibration on the earband, which is instantly converted into heat, melting the material to be processed, and finally making the earband Permanently pasting or implanting inside the mask body is the last processing step for the production of inner ear masks. Only one operator needs to place the mask body piece by piece in the mask plate, and the subsequent operations are completed automatically by the equipment.

After the main body machine outputs the mask body, the mask body sheet is conveyed to the turning mechanism by the conveyor belt structure, and the mask plate is flipped to the conveyor belt connected to the ear tape machine through the turning mechanism, and then the mask piece is conveyed to the ear tape machine through the conveyor belt. Above the first mask plate on the front, and finally put the mask sheet into the mask plate of the ear band machine by pressing down by the air cylinder, and then the ear band machine completes the welding of the ear band of the mask, edging and other actions to complete an ear band mask product. Production.

1.3 Design verification

BS EN 14683: 2019

ISTA 3A

ASTM 1980

EN ISO 10993

1.4 Design validation

Reference self-test report according to BS EN 14683: 2019

Reference Packaging and Shipping Verification Report according to ISTA 3A

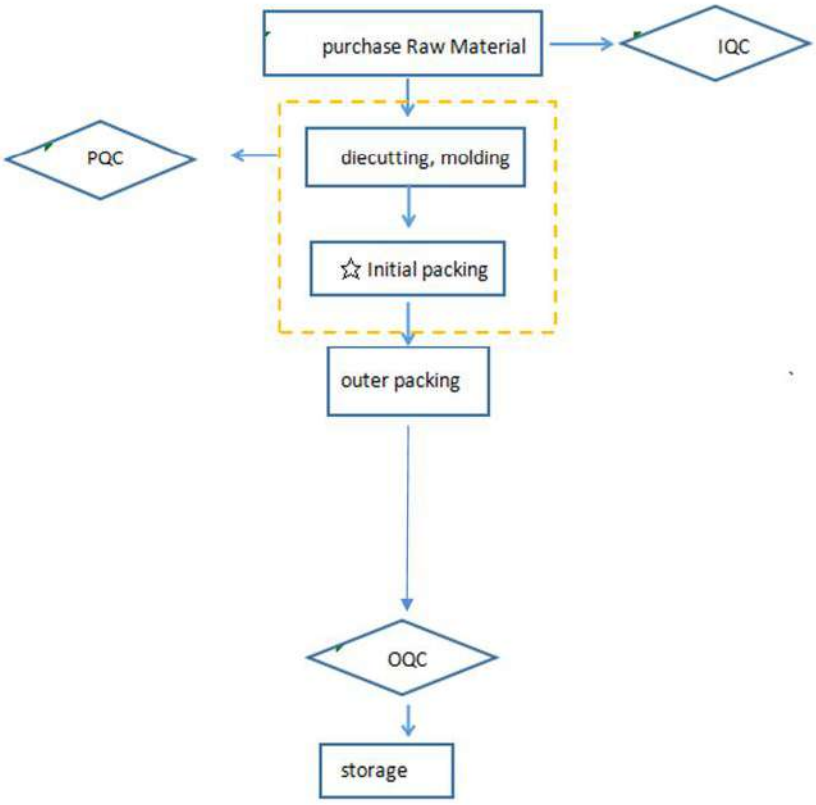
Reference Aging test report according to ASTM 1980

Reference Biological Evaluation Report according to EN ISO 10993

2. Product manufacturing procedure

2.1 Product manufacturing flow drawing

FACE MASK PROCESS FLOW



NOTE: in process of diecutting , molding , there is in the 100,000 class cleaning room
the process marked with ▲ is the special process. marked with ☆ this is the Key process

2.2 Key process control method

2.2.1Production Technology

2.2.1.1

Purchasing raw materials from the qualified suppliers, storage after pass the inspection.

2.2.1.2

It adopts a disposable mask production line for production, die-cutting, wrinkling, and masking with molding in one time. Then Check the appearance.

2.2.1.3

Initial packing process: The primary packaging is carried out in this process. After checking its appearance and tightness, it will stand by.

2.2.1.4

After packed, send into a warehouse and will be stored after passing the inspection.

At the same time, release report are signed in accordance with the release management system.

2.3 Special process validation

Initial packaging process: The tightness of primary packaging materials directly affects microbial capacity of the product.

The seal ability of the packaging material can be confirmed by the quality inspector by testing the dye permeability. Therefore, it is determined that this process is a key process. The control index of this process is the tightness of the product packaging.

2.4 Final product testing

Finished Product Sampling Items	Testing standards
Bacterial filtration efficiency (BFE)	Not less than 95%
Ventilation resistance	Not more than 40 Pa / cm2
Breaking strength at the connection point of each mask band to the mask body	Not less than 10N
Structure and size	175.5mm long 95mm wide Allowable error ± 5%
Nose clip	length is not less than 8.0cm
Microbial cleanliness	≤30cfu/g

3. Identification of all sites

3.1 Design and manufacturing site:

Address: Floor 1 and floor 2, building 2, Xixiang Jinyuan, nanbaixiang street, Ouhai District, Wenzhou City, Zhejiang Province,China

None

General safety and performance requirements checklist

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001/04

Version: A/0

Product: Disposable medical mask

Model and Size: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
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General safety and performance requirements

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
3	Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	updating. In carrying out risk management manufacturers shall: (a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.			Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
4	Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture; (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
5	In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
6	The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
7	Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	A	BS EN 14683:2019	Test reports (Appendix 1)	
8	All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
9	For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.	A	EN ISO14971:2012 EN 62366-1:2015	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
10	Chemical, physical and biological properties				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
10.1	Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion; (c) the compatibility between the different parts of a device which consists of more than one implantable part; (d) the impact of processes on material properties; (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; (g) surface properties; and (h) the confirmation that the device meets any defined chemical and/or physical specifications.	A	EN ISO14971:2012 EN 62366-1:2015 EN ISO 10993-5:2009 EN ISO 10993-10:2013 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
10.2	Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.	A	EN ISO14971:2012 EN 62366-1:2015 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
10.3	Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.	A	EN ISO14971:2012	Risk analysis report (TCF-ZJHP-001/05-2)	
10.4	Substances				
10.4.1	Design and manufacture of devices				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (5), or (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (6) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (7), in accordance with the criteria that are relevant to human health amongst the criteria established therein.	N.A 10			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
10.4.2	Justification regarding the presence of CMR and/or endocrine-disrupting substances				
	The justification for the presence of such substances shall be based upon: (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	N.A			
10.4.3	Guidelines on phthalates				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.	N.A			
10.4.4	Guidelines on other CMR and endocrine-disrupting substances				
	Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.	N.A			
10.4.5	Labelling				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	N.A			
10.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	EN ISO14971:2012 EN 62366-1:2015 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
10.6	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
11	Infection and microbial contamination				
11.1	Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids.	A	EN ISO14971:2012 EN 62366-1:2015 EN ISO 10993-5:2009 EN ISO 10993-10:2013 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
11.2	Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	N.A			
11.3	Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	A	EN ISO14971:2012 EN 62366-1:2015 EN ISO 10993-5:2009 EN ISO 10993-10:2013 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
11.4	Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.	N.A			
11.5	Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	N.A			
11.6	Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	N.A			
11.7	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	A	EN ISO14971:2012 EN 62366-1:2015 EN ISO 10993-5:2009 EN ISO 10993-10:2013 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	
11.8	The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12	Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body. 12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation. 12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.	N.A			
13	Devices incorporating materials of biological origin				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
13.1	For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
13.2	For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
13.3	For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	N.A			
14	Construction of devices and interaction with their environment				
14.1	If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	N.A			ok

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
14.2	Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; (c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; (e) the risks of accidental ingress of substances into the device; (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and (g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	A	EN ISO14971:2012 EN 62366-1:2015 EN ISO 10993-5:2009 EN ISO 10993-10:2013 BS EN 14683:2019	Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	ok

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
14.3	Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	N.A			ok
14.4	Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	N.A			
14.5	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	N.A			
14.6	Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	N.A			ok
14.7	Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	A	EN ISO14971:2012	Risk analysis report (TCF-ZJHP-001/05-2) Instruction for use	ok
15	Devices with a diagnostic or measuring function				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
15.1	Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	N.A			
15.2	The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (8).	N.A			
16	Protection against radiation				
16.1	General (a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. (b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	N.A			
16.2	Intended radiation	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. (b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.				
16.3	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	N.A			
16.4	Ionising radiation (a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	treatment. (c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. (d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.				
17	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves				
17.1	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.	N.A			
17.2	For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	N.A			
17.3	Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).				
17.4	Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	N.A			
18	Active devices and devices connected to them				
18.1	For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	N.A			
18.2	Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	N.A			
18.3	Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.	N.A			
18.4	Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	N.A			
18.5	Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	impair the operation of the device in question or other devices or equipment in the intended environment.				
18.6	Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.	N.A			
18.7	Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	N.A			
18.8	Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.	N.A			
19	Particular requirements for active implantable devices				
19.1	Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and (c) risks which may arise where maintenance and calibration are impossible, including:	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	— excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism.				
19.2	Active implantable devices shall be designed and manufactured in such a way as to ensure — if applicable, the compatibility of the devices with the substances they are intended to administer, and — the reliability of the source of energy.	N.A			
19.3	Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.	N.A			
19.4	Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	N.A			
20	Protection against mechanical and thermal risks				
20.1	Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	N.A			
20.2	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	vibrations, particularly at source, unless the vibrations are part of the specified performance.				
20.3	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	N.A			
20.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	N.A			
20.5	Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.	N.A			
20.6	Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	N.A			
21	Protection against the risks posed to the patient or user by devices supplying energy or substances				
21.1	Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.	N.A			
21.2	Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which	N.A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.				
21.3	The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.	N.A			
22	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons				
22.1	Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
22.2	Devices for use by lay persons shall be designed and manufactured in such a way as to: — ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	handling of the device and, if applicable, in the interpretation of the results.				
22.3	Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: — can verify that, at the time of use, the device will perform as intended by the manufacturer, and — if applicable, is warned if the device has failed to provide a valid result.	N.A			
23	Label and instructions for use				
23.1	General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(a)	The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(b)	The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	devices.			(TCF-ZJHP-001/02-2)	
(c)	Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(d)	Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(e)	Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(f)	Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(g)	Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(h)	Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.			Instruction for use (TCF-ZJHP-001/02-2)	
23.2	Information on the label The label shall bear all of the following particulars:				
(a)	the name or trade name of the device;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(b)	the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(c)	the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(d)	if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(e)	where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	— tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;				
(f)	where applicable, information labelled in accordance with Section 10.4.5.	N/A			
(g)	the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(h)	the UDI carrier referred to in Article 27(4) and Part C of Annex VI;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(i)	an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(j)	where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(k)	an indication of any special storage and/or handling condition that applies;	N/A			
(l)	if the device is supplied sterile, an indication of its sterile state and the sterilisation method;	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
(m)	warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(n)	if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(o)	if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;	N/A			
(p)	if the device is custom-made, the words 'custom-made device';	N/A			
(q)	an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';	N/A			
(r)	in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;	N/A			
(s)	for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.	N/A			
23.3	Information on the packaging which maintains the sterile condition of a device	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	('sterile packaging') The following particulars shall appear on the sterile packaging:				
(a)	an indication permitting the sterile packaging to be recognised as such,	N/A			
(b)	a declaration that the device is in a sterile condition,	N/A			
(c)	the method of sterilisation,	N/A			
(d)	the name and address of the manufacturer,	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(e)	a description of the device,	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(f)	if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',	N/A			
(g)	if the device is custom-made, the words 'custom-made device',	N/A			
(h)	the month and year of manufacture,	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(i)	an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and	N/A			
(j)	an instruction to check the instructions for use for what to do if the sterile	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	packaging is damaged or unintentionally opened before use.				
23.4	Information in the instructions for use The instructions for use shall contain all of the following particulars:				
(a)	the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(b)	the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(c)	where applicable, a specification of the clinical benefits to be expected.	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(d)	where applicable, links to the summary of safety and clinical performance referred to in Article 32;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(e)	the performance characteristics of the device;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
(f)	where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;	N/A			
(g)	any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(h)	specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2)	
(i)	details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;	N/A			
(j)	any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;	N/A			
(k)	the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, — identification of any consumable components and how to replace them, — information on any necessary calibration to ensure that the device operates	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	properly and safely during its intended lifetime, and — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;				
(l)	if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;	N/A			
(m)	if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;	N/A			
(n)	if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;	N/A			
(o)	an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;	N/A			
(p)	if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016 EN ISO14971:2012	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2) Risk analysis report (TCF-ZJHP-001/05-2)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	required, this information shall be made available to the user upon request;			Test reports (Appendix 1)	
(q)	for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment;	N/A			
(r)	if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device;	N/A			
(s)	information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate: — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions,	A	EN 1041:2008+A1: 2013 EN ISO 15223-1:2016 EN ISO14971:2012	Labeling (TCF-ZJHP-001/02-1) Instruction for use (TCF-ZJHP-001/02-2) Risk analysis report (TCF-ZJHP-001/05-2) Test reports (Appendix 1)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, — warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered, — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and — precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;				
(t)	in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	side-effects and risks relating to overdose;				
(u)	in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;	N/A			
(v)	warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;	N/A			
(w)	for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;	N/A			
(x)	for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;	N/A			
(y)	date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;	A	EN 1041:2008+A1: 2013	Instruction for use (TCF-ZJHP-001/02-2)	
(z)	a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is	N/A			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	established;				
(aa)	information to be supplied to the patient with an implanted device in accordance with Article 18;	N/A			
(ab)	for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	N/A			

Risk management plan

File No.: TCF-ZJHP-001/05-1

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	Alex	Zhang Xiang	2020-3-16

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-3-16

Table of contents

1. Foreword

This report is to describe the risk control carried on the Disposable medical mask manufactured by our company. All potential hazards and potential cause of each hazard have been determined in this report. Evaluations have been made on possible severity level may led by each hazard and probability of occurrence of each hazard. For unacceptable risks, necessary measures must be taken, and also evaluate the residual risk level after taking relevant measures. By taking proper measures to reduce the risks which may lead to various kinds of potential hazards to the acceptable level, and also to reduce the total amount of every kind of hazards to the acceptable level.

2. Purpose

Aim of this risk control is to carry out determination on all risks that may be led by the Disposable medical mask that have been put into production in our company, also to stipulate the necessary relative measures, in order to keep the risk level within an acceptable level. By taking risk control the company may take relative measures of continuously improving quality of the products, to meet customer stipulated or potential requirements constantly.

3. Scope

This risk analysis is applied to Disposable medical mask produced by the company.

4. Documents reference

4.1 Standards

No.	Standards	
1	EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
3	EN 1041:2008+A1: 2013	Information supplied by the manufacturer of medical devices
4	EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices
5	EN 62366-1:2015	Medical devices - Application of usability engineering tomedical devices
6	EN ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

7	EN ISO 10993-5-2009	Biological evaluation of medical devices - Part 5: Cytotoxicity test - In vitro method
8	EN ISO 10993-10:2013	Biological Evaluation of Medical Device-Part 10: stimulation and allergic reaction
9	BS EN 14683:2019	Medical face masks-Requirements and test methods

4.2 Product specification

Please refer to product specification instruction.

5. Object of risk control

5.1 Intended use of the product

For clinical staff to wear during non-invasive operation. It covers the mouth, nose and mandible of the user, providing a certain physical barrier to prevent the direct penetration of pathogens, microorganisms, particles, etc.

Intended user: clinical staff

Contraindications: None

5.2 Parameter:

Disposable medical mask		
performance	Bacterial filtration efficiency（BFE）	Not less than 95%
	Ventilation resistance	Not more than 40 Pa / cm2
	Breaking strength at the connection point of each mask band to the mask body	Not less than 10N
	Microbial cleanliness	≤30cfu/g
Product Specifications	Structure and size	175mm long 95mm wide Allowable error ± 5%
	Nose clip	length is not less than 8.0cm

5.3 Application environments

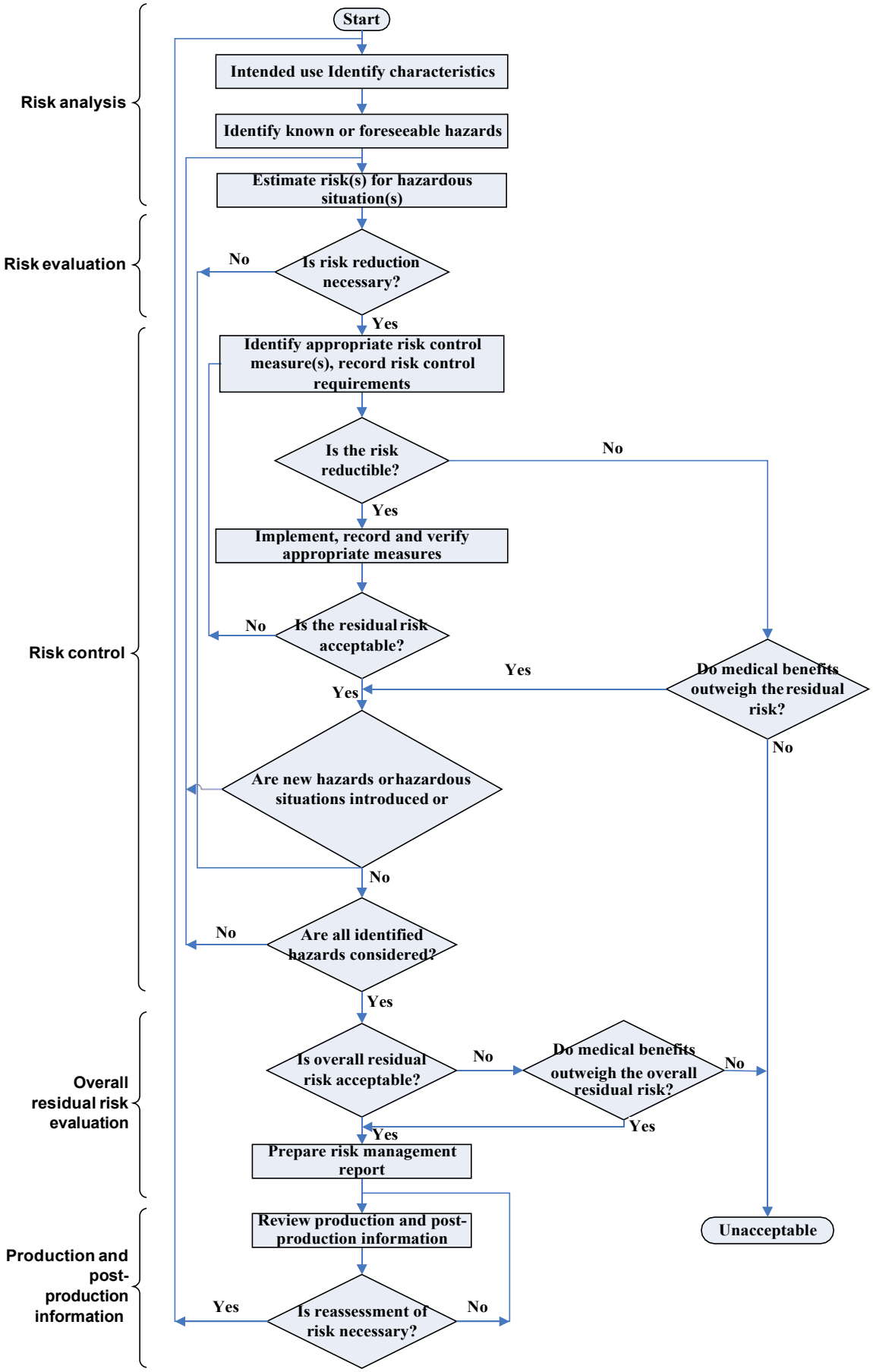
Relative humidity does not exceed 80%, and no corrosive substances

6. Members of the risk control group

Name	Position	Group division	Risk Management area of responsibility
Zhang Xiang	General manager	Leader	a) provide risk management resources required; b) approve the plan and the implementation of risk management plans; c) the approval of risk management reports.
Zhang Honglei	Management Representative	Crew	a)Be responsible for risk managers eligible to participate in the recognition. b)The Internet to collect and regulations change regularly, adverse event reporting, supervision and so on. c) Is responsible for tracking the quality of products sold, and feedback relevant information;
Zeng Yangyong	Technical Manager	Crew	a) Preparation of the implementation of the risk management plan; b) Organization and implementation of risk management activities; c) Preparation of risk management reports.
Zhuang Qianchang	Production Manager	Crew	a) provide relevant information and risks associated with the production process; b) In the production process to take risk control measures to reduce or eliminate the risk.
Liu Hui	Quality Manager	Crew	a) The results of the risk control measures for verification; b)Is responsible for the review of defective products.

7. Risk management process

Overview of the steps in the risk management process is shown in the flowchart below:


Risk analysis
Risk evaluation
Risk control
Overall residual risk evaluation
Production and post-production information
Start
Intended use Identify characteristics
Identify known or foreseeable hazards
Estimate risk(s) for hazardous situation(s)
Is risk reduction necessary?
No
Yes
Identify appropriate risk control measure(s), record risk control requirements
Is the risk reductible?
No
Yes
Implement, record and verify appropriate measures
Is the residual risk acceptable?
No
Yes
Do medical benefits outweigh the residual risk?
Yes
No
Are new hazards or hazardous situations introduced or
No
Are all identified hazards considered?
No
Yes
Is overall residual risk acceptable?
No
Do medical benefits outweigh the overall residual risk?
No
Yes
Yes
Prepare risk management report
Review production and post-production information
Is reassessment of risk necessary?
Yes
No
Unacceptable

8. Implementation of risk control process

8.1 Step1: Determination on known and foreseeable hazards

The hazard will be marked with "H……" in risk control form. (see the risk analysis report)

Information resources: the following information can be regarded as potential hazard list

·Available risk analysis report on homologous product

·Investigations on developer of the product

·Determinations made by medical experts

·Analysis medical devices report from foreign authorities

·Site documents, complains and accident records gained from homologous products which have been put into use.

8.1.1 Estimation on severity level of each hazard

Severity level of each hazard must be estimated and semi-quantitative judged (in the form of serious level) by the medical expert

Severity level	Code	Description
Negligible	S1	Inconvenience or temporary discomfort
Minor	S2	Results in temporary injury or impairment not requiring professional medical intervention
Serious	S3	Results in injury or impairment requiring professional medical intervention
Critical	S4	Results in permanent impairment of life-threatening injury
Catastrophic	S5	Results in patient death

8.1.2 Judgment of potential causes of each hazard

Members of the group shall at first find the potential causes directly base on their professional knowledge.

The founded hazard causes must be recorded in "Cause" column of risk control report, and mark with "C…". (see the risk analysis report)

8.1.3 Estimation on probability of occurrence of each cause

Occurrence probability of each potential cause must be estimated. In addition, the relative information resources are:

- Using experience of equivalent products (e.g. service statistic data)
- Customer complain
- Investigation on service life of self product
- Expert judgment

Such estimation carried out by relative personnel can be divided into following 5 categories:

Level	Code	Probability of occurrence
Improbable	P1	$<10^{-5}$
Remote	P2	10^{-4}~10^{-5}
Occasional	P3	10^{-3}~10^{-4}
Probable	P4	10^{-2}~10^{-3}
Frequent	P5	$\geq 10^{-2}$

8.2 Step2: Risk estimation (before taking control measures)

Two risk factors were concluded in first hazard/cause item: hazard severity level and occurrence probability, relative risk. Three "risk area" can be defined according to advise of EN ISO14971:2012.

1. Not acceptable area: U
2. Wide acceptable area: A

8.3 Step3: Risk evaluation

Probability of occurrence	Severity level				
	Negligible (S1)	Minor (S2)	Serious (S3)	Critical (S4)	Catastrophic (S5)
Frequent (P5)	U	U	U	U	U
Probable (P4)	U	U	U	U	U
Occasional (P3)	A	A	U	U	U
Remote (P2)	A	A	A	U	U
Improbable (P1)	A	A	A	A	A

U: Unacceptable risk

A: Insignificant risk

All risks estimated for each hazard/cause must be recorded in column of risk control form in the form of risk range (U, A) categories, and noted separately whether control measures are available.

8.4 Step4: Taking risk control measures

If no control measures are available for estimated risks, it is unacceptable, then control measures must be taken for each hazard cause. If several control measures were designed at

the same time, then the effect will be the result when all relative control measures are taken. All the measures must be recorded in the column “relative measures” of risk control form, and marked with “M….”. (see the risk analysis report)

8.5 Step5: Evaluation on residual risks

The severity level and/or occurrence probability will be decreased after taking control measures. Sometime it cannot be determined in detailed quantity that in which level a group of relative control measures can decrease the risk factors (severity level or occurrence rate). The evaluation on residual risks is the summing-up of analysis of the group members based on their individual professional knowledge.

All changing of each category must be recorded in the column “residual risk” of risk control form. (see the risk analysis report)

The residual risk of each hazard/cause may base on the determined risk area (U, A) stipulated in the previous chapter.

8.6 Step6: Risk/benefit analysis

R does not mean that the aim has been reached, it can be acceptable only when it is technically unpractical or the expense raised the further risk decrease measures is larger than the benefit it will bring, and also the benefit is larger than the risk. If R range is the result of risk decreasing, then an explanation must be made on why the further risk decreasing is unpractical.

8.7 Step7 Result of risk control

As showing in the risk control form (see the risk analysis report), the residual risks of each hazard/cause shall be reduced to acceptable or R range, total amount of residual individual risk shall also be regarded as acceptable.

8.8 Step8 Production and post-production information

Collect and review information about the medical device or similar devices in the production and post-production phases.

1. Information Source During and After Production

1) Production feedback from production department；

2) After-sales service from sales department；

3) Public information of other similar medical equipment on the market;

4) Influences brought by new or revised rules and standards.

2 Collection, Review and Treatment of Information during and After Production

1) In each quarter, production department collects and summaries Disposable medical mask production conditions, and provides the related information to product owner in research and development department;

2) In each quarter, after-sales group collects and summaries Disposable medical mask after-sales conditions, and provide the related information to the product owner;

3) Product owner should pay a close attention to the market, and collect and analyze the public information of other similar medical equipment whenever possible;

4) Product owner should collect national laws and standards, and make a response to their affections;

5) Product owner should evaluate the information involving safety, in particular, whether the risk or danger never been realized before is presented; whether one or more estimated risks are not acceptable any longer.

If any of the above cases occurs, it is required to evaluate the influence of the previously-implemented risk management activities, to feed the result back to risk management process, and to further evaluate risk management document of medical equipment. If there is one or more residual risks being presented, or their acceptability has been changed according to the result, it is required to evaluate the influence of the previously-implemented risk management control measures.

6) “Collection, Evaluation and Treatment Report to Production and After-Production Information of Medical Equipment” should be formed based on the results of collection, evaluation and treatment to the production and after-production information, and brought into the risk management document.

9. Conclusion on risk control

As displayed in risk management report (see TCF-ZJHP-001/05-2, A/0), a detailed risk analysis has been carried out and evaluation has been made on all items that may cause hazards. All risks are under control and acceptable When new documents and data are used, the new round of risk analysis shall be carried out, for example, along with time passing, the risk may change and production process and product structure may be change accordingly. New risk may occur or to be determined for the first time.

10. Appendix

-Risk management report (TCF-ZJHP-001/05-2, A/0)

Risk management report

File No.: TCF-ZJHP-001/05-2

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-3-16

Chapter I Summary

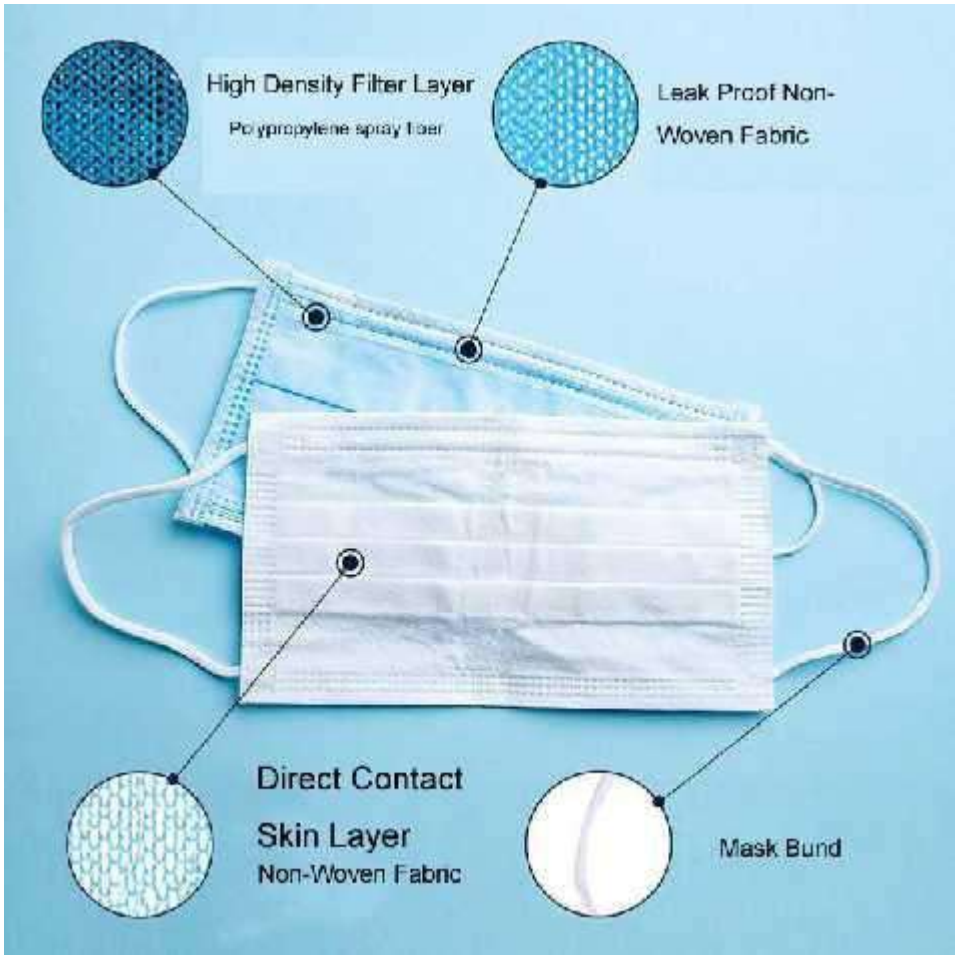
1. Product description

Device name: Disposable medical mask
Model: 17.5*9.5cm

1.1 Indication for use
For clinical staff to wear during non-invasive operation. It covers the mouth, nose and mandible of the user, providing a certain physical barrier to prevent the direct penetration of pathogens, microorganisms, particles, etc.
Intended user: Clinical staff
Contraindications: None

1.2 Normal conditions of use:
Relative humidity does not exceed 80%, and no corrosive substances

1.3 Structure



1.4 Basic Performance:

Disposable medical mask		
performance	Bacterial filtration efficiency （BFE）	Not less than 95%
	Ventilation resistance	Not more than 40 Pa / cm2
	Breaking strength at the connection point of each mask band to the mask body	Not less than 10N
	Microbial cleanliness	≤30cfu/g
Product Specifications	Structure and size	175.5mm long 95mm wide Allowable error ± 5%
	Nose clip	length is not less than 8.0cm

2. Shelf life

24 Months

3. Brief description of the implementation of risk management

Disposable medical mask began to be planned in 2019. At the same time of project establishment. We planned risk management activities for the product and formulated a risk management plan.

The risk acceptance plan identified in the risk management plan requires review of risk management activities during product design and development (including trial production), responsibilities and authorities of personnel involved in risk management activities, and methods of obtaining production and post-production information Arranged.

The company formed a risk management team to determine the risk management leader for the project. Ensure that the project's risk management activities are effectively implemented in accordance with the risk management plan.

During the product design and project development phase, the risk management team conducted a risk management review and formed relevant risk management documents.

4. Reference

No.	Standards	
1	EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

3	EN 1041:2008+A1: 2013	Information supplied by the manufacturer of medical devices
4	EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices
5	EN 62366-1:2015	Medical devices - Application of usability engineering tomedical devices
6	EN ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
7	EN ISO 10993-5-2009	Biological evaluation of medical devices - Part 5: Cytotoxicity test - In vitro method
8	EN ISO 10993-10:2013	Biological Evaluation of Medical Device-Part 10: stimulation and allergic reaction
9	BS EN 14683:2019	Medical face masks-Requirements and test methods

5. Risk Management Responsibilities and Authorization

1) Management Representatives provide appropriate resources for risk management and assume leadership responsibility for risk management. Ensure that the personnel assigned to risk management, implementation and evaluation are trained and qualified, and that the risk management performers have the appropriate knowledge and experience.

2) The R & D department is responsible for risk management activities in the product design and development process, forming relevant records of risk analysis, risk evaluation, risk control, and comprehensive residual risk analysis and evaluation, and preparing a risk management report.

3) The quality control department, foreign trade department, sales department, production department and other relevant departments are responsible for analyzing all known and foreseeable hazards from the perspective of product realization, and collecting information after production and post-production, and timely feedback to the R & D department for risk assessment. , If necessary, conduct a new round of risk management activities.

4) The members of the R & D department and the review team regularly review the results of risk management activities and are responsible for their correctness and effectiveness.

5) The office is responsible for the organization of all risk management documents.

6. Members of risk management group

The group of risk analysis consists of the following person:

Name	Position	Group division	Risk Management area of responsibility
Zhang Xiang	General manager	Leader	a) provide risk management resources required; b) approve the plan and the implementation of risk management plans; c) the approval of risk management reports.
Zhang Honglei	Management Representative	Crew	a)Be responsible for risk managers eligible to participate in the recognition. b)The Internet to collect and regulations change regularly, adverse event reporting, supervision and so on. c) Is responsible for tracking the quality of products sold, and feedback relevant information;
Zeng Yangyong	Technical Manager	Crew	a) Preparation of the implementation of the risk management plan; b) Organization and implementation of risk management activities; c) Preparation of risk management reports.
Zhuang Qianchang	Production Manager	Crew	a) provide relevant information and risks associated with the production process; b) In the production process to take risk control measures to reduce or eliminate the risk.
Liu Hui	Quality Manager	Crew	a) The results of the risk control measures for verification; b)Is responsible for the review of defective products.

7. Risk Analysis Plan

Please see the document TCF-ZJHP-001/05-1.

Chapter II Risk Analysis

1. Acceptable criteria

1.1 Evaluation criteria of severity level

In the risk analysis, there are two risk levels defined:

- Acceptable risk
- Unacceptable risk

The Risk Priority Number (RPN) is defined by the combination of the probability level and the severity level (RPN = Probability * Severity)

Table 1 Severity assessment scale

Level	Code	Description
Negligible	S1	Inconvenience or temporary discomfort
Minor	S2	Results in temporary injury or impairment not requiring professional medical intervention
Serious	S3	Results in injury or impairment requiring professional medical intervention
Critical	S4	Results in permanent impairment of life-threatening injury
Catastrophic	S5	Results in patient death

1.2 Evaluation criteria of probability of occurrence

Table 2 Estimation on probability of occurrence of hazards

Level	Code	Probability of occurrence
Improbable	P1	$<10^{-6}$
Remote	P2	10^{-4}~10^{-6}
Occasional	P3	10^{-2}~10^{-4}
Probable	P4	10^{-1}~10^{-2}
Frequent	P5	1~10^{-1}

The probability of the occurrence of risk is based on the clinical use of products, to be

determined according to Collection of during and after production information, product clinical tracking information statistics and evaluation.

1.3 Risk Acceptability Matrix

Product risk assessment based on the following formula: risk level= Probability of occurrence×severity level

Table 3Risk Acceptability Matrix

Probability of occurrence	Severity level				
	S1	S2	S3	S4	S5
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent (P5)	A	U	U	U	U
Probable (P4)	A	A	U	U	U
Occasional (P3)	A	A	U	U	U
Remote (P2)	A	A	A	A	U
Improbable (P1)	A	A	A	A	A

Note: A: Acceptable risk; U: Unacceptable risk

1.4 Risk acceptability criterion

See Table 4 of acceptable criterion of the product manufactured by our company after comprehensive risk level assessment.

Table 4 Risk evaluation

Risk value	Acceptable criterion
1-8	Acceptable risks
9-25	Unacceptable

2. Identification of qualitative and quantitative characteristics

No.	Features that may affect safety	Applicable or not	Feature judgment
1	C.2.1 What is the intended use of the medical device is? How to use the medical equipment?	—	For clinical staff to wear during non-invasive operation. It covers the mouth, nose and mandible of the user, providing a certain physical barrier to prevent the direct penetration of pathogens, microorganisms, particles, etc. User / operator: Clinical staff. Clinical environment: hospital. □1. Energy Hazard ■2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards □ 5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging
2	C.2.2 Whether the medical device is intended to be implanted?	No	
3	C.2.3Are medical devices intended to contact with the patient or other person?	Yes	Mask and mask band will contact patient (short-term contact) □ 1. Energy Hazard ■ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards □ 5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging
4	C.2.4 What materials or components do the medical device apply, or be used jointly with medical device or in contact with?	No	
5	C.2.5 Is there energy supplied to or obtained from the patient?	No	
6	C.2.6 Is there any substance supplied to or obtained from the patient?	No	
7	C.2.7 Whether dose the medical device deal with biological material for subsequent re-use, infusion / blood or transplant?	No	

No.	Features that may affect safety	Applicable or not	Feature judgment
8	C.2.8Is medical device supplied sterile or expected to be sterilized by the user, or by other microbiological control method?	No	
9	C.2.9 Is medical equipment intended to be cleaned and disinfected by the user?	No	
10	C.2.10 Is medical device intended to improve the patient's environment?	No	
11	C.2.11 Is medical device intended to conduct measurements?	No	
12	C.2.12 Is medical device intended to conduct analysis and processing?	No	
13	C.2.13 Is medical device intended to be used jointly with other medical devices, medicine or other medical techniques?	No	
14	C.2.14 Is there any unwanted energy or substance output of the medical device?	No	
15	C.2.15Is medical device sensitive to the environment?	No	
16	C.2.16 Is there any impact of medical device on the environment?	Yes	The equipment conducts electromagnetic radiation disturbance to the outside □ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards ■5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging
17	C.2.17 Are there any consumption or accessories of medical device?	No	
18	C.2.18 Is medical device intended to be maintained or calibrated?	No	
19	C.2.19 Whether dose the medical device need to be equipped with	No	

No.	Features that may affect safety	Applicable or not	Feature judgment
	software?		
20	C.2.20 Is there storage life limitation of the medical device?	Yes	□ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards □5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) ■ 8. Hazards caused by functional failure, maintenance or aging
21	C.2.21 Is there delay or long-term effect of medical device?	No	
22	C.2.22 Which kind of mechanical forces dose the medical device bears?	No	
23	C.2.23 What determines the lifetime of the medical device?	Yes	Each use time, equipment maintenance, aging of plastic connections and aging of electronic components of the instrument □ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards □5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) ■ 8. Hazards caused by functional failure, maintenance or aging
24	C.2.24 Is the medical device intended to be used disputably?	No	
25	C.2.25 Whether does the medical device need safe decommission or disposal?	Yes	Dispose of the instrument in accordance with local laws and regulations □ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards ■5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging
26	C.2.26 Whether dose the installation or use of medical devices require special training or special skills?	No	
27	C.2.27 How to provide safe use?	Yes	It will be marked on the device or in the random file (instruction manual) will provide relevant safety information and warning information, and train the end-users □ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards ■ 5. Environmental hazards □ 6. Information hazards □ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging

No.	Features that may affect safety	Applicable or not	Feature judgment
28	C.2.28 Whether does the new manufacturing process need to be established or introduced?	No	
29	C.2.29 Does the successful use of medical device depend on human factors, such as the user interface? C.2.29.1 Whether does the user interface design features cause mistake in using?	No	
30	C.2.29.2 Whether can the medical device be used in the environment of using mistake caused by distraction?	No	
31	C.2.29.3 Is there any connection or attachment of the medical device?	No	
32	C.2.29.4Is there any control interface of the medical device?	No	
33	C.2.29.5 Does the medical device display information?	No	□ 1. Energy Hazard □ 2. Biological Hazard □ 3. Hazards Related to the Use of Medical Devices □ 4. Software hazards □5. Environmental hazards □ 6. Information hazards ■ 7. Harm of improper or overly complicated user interface (ergonomics) □ 8. Hazards caused by functional failure, maintenance or aging
34	C.2.29.6 Whether is the medical device controlled by the menu?	No	
35	C.2.29.7 Whether is the medical device used for people with special needs?	No	
36	C.2.29.8 Whether does the user interface enable the user to start up?	No	
37	C.2.30 Is there any alarm system of the medical device?	No	
38	C.2.31 Under which condition, the medical device may be intentionally	No	

No.	Features that may affect safety	Applicable or not	Feature judgment
	misused?		
39	C.2.32 Whether dose the medical device save the important data for patient care?	No	
40	C.2.33 Is the medical device intended to be used as mobile or portable?	No	
41	C.2.34 Dose the use of medical device depend on its basic performance?	No	
42	How to involve using equipment safely in a single failure state	No	

Chapter III Risk Assessment and Control

1. Risk assessment and risk control measures

No.	Hazards		Before taking measure			Measures taken	After taking measure			verification	New hazard happen or not	Risk is acceptable or not
	General	Identify hazards	Severity	Probability	acceptability		Severity	Probability	acceptability			
D4. Environmental hazards and contributory factors												
1	Storage or operation outside prescribed environmental conditions	Influence the effect of the product	S2	P4	U	Add the information for storage or operation outside prescribed environmental conditions in the manual	S2	P2	A	Design procedure	-	Acceptable
2	Contamination due to waste products and /or device disposal	Incorrect disposal could lead to environmental pollution	S2	P2	U	explained in manual	S2	P1	A	Design procedure	-	Acceptable
D6. Hazards related to the use of the device and contributory factors												
1	Inadequate labeling	Cause inaccurate use	S4	P2	U	1.Label design in accordance with the requirements of CE implementation； 2. Put The product information into the document management procedure, all the information are prepared, review, approval. 3. Track the usage of products regularly, collect and change the related	S4	P1	A	document management procedure Product Track procedure	-	Acceptable

						error information in time. 4. QC inspection before delivery.						
2	Inadequate operating instructions： • inadequate specification of accessories • inadequate specification of pre-use checks • over-complicated operating instructions • inadequate specification of service and maintenance	Inadequate operating instructions may cause wrong use of the device influencing the effect.	S4	P2	U	1. User manual in accordance with the requirements of CE implementation； 2. Put The product information into the document management procedure, all the information are prepared, review, approval. 3. Track the usage of products regularly, collect and change the related error information in time. 4. QC inspection before delivery.	S4	P1	A	document management procedure Product Track procedure	-	Acceptable
3	Use by unskilled/untrained personnel	Unskilled/untrained personnel may cause wrong use of the device influencing the effect.	S3	P3	U	1. explained in manual 2. add warning label: read IFU before use	S3	P2	A	Design procedure	-	Acceptable
D8. Hazards arising from functional failure, maintenance and ageing												
1	Inadequate packaging(contamination and /or deterioration of the device)	Improper packaging may cause damage of device	S3	P2	A	1. Production in accordance with the packaging requirements for packaging 2. QC in accordance with the requirements of the pa						Acceptable

Chapter IV Review of overall residual risk acceptability and risk benefit analysis

After all risk control measures, there is no risk item with an unacceptable level of risk and "ALARP". All operations and risks that cause serious hazards are notified to the operator through warning messages in the instruction manual.
Residual risk assessment is performed by checking the tables in Chapter 2. The residual risks of all risk items are acceptable.
According to the results of the risk control in the "Table 2 Risk Analysis and Management Summary Table", it can be seen that there are no unacceptable (U) level risk items after the risk control measures are currently expected and known.
The risk level is the risk items of "ALARP" have been evaluated by experts' residual risks, and all the residual risks are acceptable. No risk / benefit analysis is required.

Chapter V Production and after production information

Production and after production information can be accessed through Risk Management Control Process. .

Information Collection Methods During and After Production

1 Information Source During and After Production

1) Production feedback from production department；

2) After-sales service from sales department；

3) Public information of other similar medical equipment on the market;

4) Influences brought by new or revised rules and standards.

2 Collection, Review and Treatment of Information during and After Production

1) In each quarter, production department collects and summaries Disposable medical mask production conditions, and provides the related information to product owner in research and development department;

2) In each quarter, after-sales group collects and summaries Disposable medical mask after-sales conditions, and provide the related information to the product owner;

3) Product owner should pay a close attention to the market, and collect and analyze the public information of other similar medical equipment whenever possible;

4) Product owner should collect national laws and standards, and make a response to their affections;

5) Product owner should evaluate the information involving safety, in particular, whether the risk or danger never been realized before is presented; whether one or more estimated risks are not acceptable any longer.

If any of the above cases occurs, it is required to evaluate the influence of the previously-implemented risk management activities, to feed the result back to risk management process, and to further evaluate risk management document of medical equipment. If there is one or more residual risks being presented, or their acceptability has been changed according to the result, it is required to evaluate the influence of the previously-implemented risk management control measures.

6) “Collection, Evaluation and Treatment Report to Production and After-Production Information of Medical Equipment” should be formed based on the results of collection, evaluation and treatment to the production and after-production information, and brought into the risk management document.

Chapter VI Risk Management Review

1. Risk management review input

1) Risk acceptance criteria-see Chapter II

2) Risk management documents

Risk Management Plan

Security characteristics analysis table

Risk assessment, implementation and verification of risk control measures

Residual risk assessment record

3) Relevant standards

2. Completion of risk management plan

The review team checked the completion of the risk management plan one by one. After checking the relevant risk management documents, it was concluded that the risk management of the product had been basically implemented.

3. Acceptable review of comprehensive residual risk

The review team conducted a comprehensive analysis of all remaining risks, and considered the role of all individual residual risks. The review results concluded that the comprehensive residual risk of the product was acceptable. The following are specific evaluation aspects:

1) Does the risk control of individual risks have conflicting requirements?

Conclusion: No conflicting situation has been found in the existing risk control.

2) Review of warnings (including excessive warnings?)

Conclusion: The warnings are clear and in compliance with the regulations.

3) Review of the specification (including whether there are any contradictions and whether it is difficult to comply)

Conclusion: The product manual complies with the requirements of Decree No. 10 and product-specific safety standards, and the description of related product safety is clear and easy to understand, and it is easy for users to read.

4) Compare with similar products

Conclusion: higher than the level of peer products.

5) Conclusion of the review team

Conclusion: After analyzing the above aspects, the risk management review team unanimously evaluated that the comprehensive residual risk of this product is

acceptable.

4. Reviewed risk management documents

Risk management plan

Security Feature Analysis Form

Risk assessment, implementation and verification of risk control measures

Residual risk evaluation record

Chapter VII Conclusion of risk management review

After the review of the Disposable medical mask, the risk management review team comes to the conclusion:

－Risk management plan has been properly implemented.

－Overall residual risk is acceptable.

－Have appropriate methods to obtain information related to production and after production. Start the dynamic risk management program at the right moment. All remaining risks are within the acceptable of the acceptable risk criteria, and the benefits are more than risks.

Summary of Pre-clinical test

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001/06-1

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
Zhang Honglei	**Alex**	**Zhang Xiang**	**2020-3-16**

Document Revision History

REV	ECN	DESCRIPTION	ORIGINATOR	DATE
A/0	-	Initial		2020-3-16

1. Device description

Device name: Disposable medical mask

Model: 17.5*9.5cm

2. Indication for use

For clinical staff to wear during non-invasive operation. It covers the mouth, nose and mandible of the user, providing a certain physical barrier to prevent the direct penetration of pathogens, microorganisms, particles, etc.

Intended user: Clinical staff
Contraindications: None

3. Performance

Disposable medical mask		
performance	Bacterial filtration efficiency（BFE）	Not less than 95%
	Ventilation resistance	Not more than 40 Pa / cm2
	Microbial cleanliness	≤30cfu/g
	Breaking strength at the connection point of each mask band to the mask body	Not less than 10N
Product Specifications	Structure and size	175.5mm long 95mm wide Allowable error ± 5%
	Nose clip	length is not less than 8.0cm

4. Summary of Safety and Performance Testing

Test items	Test method/standard	Test Result	Conclusion
Performance	BS EN 14683:2019	Pass	After verification, meet the standard requirements and meet the design requirements
Shelf life	ASTM F1980	Pass	After verification, meet the standard requirements and meet the design

			requirements
Usability validation	EN 62366-1:2015	Pass	After verification, meet the standard requirements and meet the design requirements
Transport simulation validation	ISTA 3A	Pass	After verification, meet the standard requirements and meet the design requirements

Biological Evaluation Report

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001/06-2

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

Issued By	Reviewed By	Approved By	Effective Date
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1. Patient contact material analysis

As the structure drawing above, mask and mask band contact patient, the material is listed in table 1:

Table 1: Patient Contacting Materials

No.	Component	Model	Contacting Classification	Material	Disposable or Reusable
1	mask		Surface contacting, Less than 24 hours		**Disposable**
2	mask band		Surface contacting, Less than 24 hours		**Disposable**

2. Biocompatibility

Per ISO 10993-1, the worst-case categorization based on intended use for all the contacting materials which are the subject of this submission is surface-contacting, limited exposure (less than 24 hours). Based on the categorization the following biocompatibility tests are required:

- Toxicity
- Skin Sensitization
- Skin Irritation

The test article sample extracted according to ISO 10993-12: 2012. Specific sample extraction method and testing data can be found in the references listed in the following tables. Please notice that all the extracts were used immediately after extraction. All the extracts of the test and controls were clear and without any special treatments. Test was performed on test articles that were representative of the subject device. Results demonstrate that the probe are biocompatible when used as intended. Please refer to Table 2 for results summary of the biocompatibility testing on them, and find detailed information in the test reports.

Table 2: Summary of Biocompatibility Testing

Test/ Standard	Component	Test Result	Conclusion	Report Location
in vitro cytotoxicity test (MTT method, MEM with 10% FBS) per ISO 10993-5	All	No potential cytotoxicity	Pass	Refer to file Biocompatibility Report _Cytotoxicity
Skin Sensitization Test (Guinea Pig Maximization Test with 0.9% sodium chloride injection extract) per ISO 10993-10:2010 test methods.	All	No sensitization observed (test sample score 0)	Pass	Refer to file Biocompatibility Report _Skin Sensitization with 0.9% sodium chloride injection

				extract
Skin Sensitization Test (Guinea Pig Maximization Test with sesame oil extract) per ISO 10993-10:2010 test methods	All	No sensitization observed (test sample score 0).	Pass	Refer to file Biocompatibility Report _Skin Sensitization with sesame oil extract
Skin Irritation Test (sesame oil extract) per ISO 10993-10:2010 test methods	All	Negligible (no observed primary irritation, test sample score 0).	Pass	Refer to file Biocompatibility Report _Skin Irritation with sesame oil extract
Skin Irritation Test (0.9% sodium chloride injection extract) per ISO 10993-10:2010 test methods.	All	Negligible (no observed primary irritation, test sample score 0).	Pass	Refer to file Biocompatibility Report _Skin Irritation with 0.9% sodium chloride injection extract

3. Conclusion

According to analysis results, all the Patient Contacting Materials shows no cytotoxicity, irritation response were negligible and no sensitization.

Vigilance system

According to Medical Device Directive 93/42/EEC

File No.: TCF-ZJHP-001/08

Version: A/0

Product: Disposable medical mask

Model: 17.5*9.5cm

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1、Purpose

This document is formulated in accordance with MDD 93/42/EC indicators, to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type adverse incident being repeated in different places at different times. It will also ensure that any incidents falling within the criteria for reporting will be identified and passed on to the Competent Authority within the stipulated times. Products quality accidents can be effectively identified, take full control to warning system.

2、Application

2.1 The document refers to incidents occurring within the Members States of European Community and all other States within the European Economic Area (EEA) with regard to;
2.2 It applies to quality accidents for products with the CE mark within global range;
2.3 Company has obligations to inform and report to national statutory bodies for occurred quality accidents.
2.4 If incidents that occur outside the EEA lead to corrective action relevant to CE marked medical devices that are offered for sale or are used within the EEA, then our company should notify the relevant Competent Authorities.

3、Responsibilities

3.1 Responsibilities of EU authorized representatives: Immediately inform competent authorities of the European Union when receive company's quality accidents reports;
3.2 Dealers' responsibilities: pass information of customer complaints and occurred quality accidents in time;
3.3 Responsibilities of company
3.3.1 Sales department is responsible for collecting occurred quality accidents information, at the same time, transfer relevant information to company's relevant functional departments and pass adopted corrective measures feedback to customers, and it is responsible for keeping sales records;
3.3.2 Management representatives are responsible for verification work of quality accidents feedback, and pass the accidents and adopted corrective measures to EU authorized representatives in a timely manner;
3.3.3 The general manager has the final decision for products quality accident investigation, assessment, notification and recall activities;
3.3.4 Technical department is responsible for organizing and implementing corrective measures, and is responsible for control of quality documents, as well as is responsible for organizing implementation of technical aspects in products and collection of relevant information;
3.3.5 If necessary, relevant functional departments is responsible for informing announcement agency according to < Announcement Agencies Management Procedure of Significant Changes in Product and System >;
3.3.6 All employees (including distributors, EU representatives, etc.) must understand the basic contents of the procedure.

4、Procedure

4.1 Transmission of quality accidents

4.1.1 Sales department and distributors should inform management representatives about quality accidents in detailed and accurate way.

4.1.2 Management representatives will organize to investigate with relevant personnel regarding received information from sales department or EU authorized representatives; decide whether to start products warning system with the feedback information as quality accidents;

4.1.3 The general manager identifies accident types, organize staffs to collect incidents related quality accidents data and conduct preliminary technical assessment.

4.2 Accident types identification

4.2.1 The company's products are involved in this accident;

4.2.2 Incidents were caused by the company itself or may be caused.

4.3 When quality accidents have the following characteristics after general manager’s approval, management representatives are responsible for informing announcement agency according to < Announcement Agencies Management Procedure of Significant Changes in Product and System >:

4.3.1 Any failure or damage of products occurred, major quality accidents that will result in death of patients or users;

4.3.2 Any failure or damage of products occurred, causing serious injury to the health of patient or users.

a) Serious life-threatening diseases and injuries;

b) Permanent loss of body function or permanent damage to body structure;

c) Require medical treatment or surgery can help to prevent loss or injury.

4.3.3 Direct causes of quality accident are caused by our products;

4.3.4 The potential accidents of defective products.

4.4 After occurrence of quality accident, technical manager must organize relevant personnel to collect, prepare relevant information on the quality accidents

a) Preliminary assessment results of accidents;

b) Other evidence and related information of company’s accident;

c) Evidence of similar accidents from other companies;

d) Points of view from medical experts or doctors (Based on available evidence);

e) Invalidity of product features or performance or deterioration of the situation;

f) Products don not appear functional or performance products failure or deterioration situation, but certain features may lead to accidents, then they will be treated as accidents and inform;

g) Any inaccuracies, omissions or deficiencies in existed product manual.

The above mentioned information must be submitted to competent authorities together with the quality incident reports.

4.5 Time limit of quality accidents reports and potential quality accidents reports:

a) Accidents: It must inform corresponding competent authorities within 10 working days;

b) Quasi-accidents: It must inform corresponding competent authorities within 30 working days;

.4.6 Implement controlling processes

4.6.1 When accident occurred, management representatives shall promptly notify EU authorized representatives.

4.6.2 In the organization of general manager, relevant personnel must collect solid information in specified time;

4.6.3 The general manager is responsible for the completion of initial accidents reports, management representatives will notify appropriate authorities on behalf of EU authorized representatives (statutory bodies, see Annex 1);

4.7 Form of report notification

4.7.1 If it occurred in EC countries, the company should report to competent authorities of the country about quality accidents;

4.7.2 If it occurred outside EC countries, the company should:

a) products which had been take corrective measures, it should report to competent authority of that place;

b) When applicable, as for products, it should report to competent authorities of the country in EC.

4.7.3 When appropriate, warning system should notify quality accidents to EC authorized representatives and other agencies, as well as to inform the authorized certification organization.

4.8 Initial accident investigation report refers to Annex.

4.9 Implement investigation of final quality incident

4.9.1 Based on initial report, the general manager will organize further investigation and assessment to accidents, relevant functional departments report to governing authorities about investigation progress according to <Announcement Agencies Management Procedure of Significant Changes in Product and System>;

4.9.2 If the company can not do quality accident investigation, it shall promptly notify competent authorities without any delay.

4.10 Measurement

4.10.1 The company takes necessary corrective and preventive measures according to final conclusions of survey, decide to carry out measures such as product recalls through discussions with competent authorities;

4.10.2 The general manager will complete quality accident investigation report with the help of EU authorized representatives, which includes final conclusion of investigation and adopted corresponding measures, and will be reported to competent authorities by EU authorized representatives.

4.10.3 Measures should include the following aspects:

a) Reasons that not to take any corrective and preventive measures;

b) Make inspection and tracking to products that had already flow into the market;

c) Providing information to users, such as publish warning notice;

d) Take improving measures for future products;

e) Take corrective measures to products that had already flow into the market;

f) Implement products recall.

4.11 Contact way with EU authorized representative

4.11.1 Management representatives are responsible for liaison work with EU authorized representatives, purpose is to ensure a timely and effective communication with EU authorized representatives for documents, and must always pay attention to whether address, telephone number change or not.

4.11.2 QC department is responsible for informing EU authorized representatives within 10 working days about changes of officially required relevant CE technical documents, quality documents, or such kind of documents.

4.11.3 Responsibilities of EU authorized representatives

4.11.3.1 They are responsible for registration of products with CE mark to competent authorities their country;

4.11.3.2 Save technical documents of CE mark products and quality management system documents, document retention period shall in accordance with MDD regulation; it should be at least 5 years from the last batch of the manufacture date;

4.11.3.3 They are responsible for collecting all information of CE mark products in EU (customer complaints and change information of European Union laws and regulations), and timely send back to company;

4.11.3.4 EC quality accidents in EC shall be promptly notified to the company and assistant company to deal with medical apparatus accidents, and responsible for reporting initial and final quality accidents reports to competent authorities of the country in EU.

4.11.4 Company responsibilities

4.11.4.1 Ensure to provide effective CE technical documents and quality management system documents to EU authorized representatives;

4.11.4.2 Product Changes shall promptly notify EU authorized representatives;

4.11.4.3 Quality accident

a) Accidents within EC should be promptly investigated together with EU authorized representatives, and complete the initial and final quality incident reports, and then report to competent authorities within stipulated time;

b) Accidents outside of EC shall be promptly notified EU authorized representatives to decide whether to report to authorities or not.

4.11.4.4 To ensure smooth contacting channels, it is necessary to inform EU authorized representatives timely about changes of contact addresses and telephone numbers.

5. Related documents

List of vigilance contact points within the National Competent Authorities

6. Quality records

None

7. Reference

MEDDEV 2.12/1 rev.8 Guidelines on a medical devices vigilance system **January 2013**

Additional guidance on MEDDEV 2.12/1 rev.8 **July 2019**