EC Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

on Class I Medical Device, Annex VII
Doc. No. CJW20EU0514-71

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

Applicant Name: Zhongshan First Mountain Electrical Appliance Company

Limited

Address: NO.31 Hesui Industrial Blvd Suicheng Village, Dongfeng

Town, Zhongshan, Guangdong Province, China

Product Description: Disposable Medical Masks (Non sterile)

Models/Type References: F001

Standard(s)/Directive(s):

EN ISO 13485:2016

EN ISO 14971:2012

EN 1041:2008

EN ISO 15223-1:2012

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 62366:2008

EN 14683:2019

Conformity assessment

procedure:

EC Declaration of Conformity (Annex VII) + Technical

Files)

EC representative:

Share Info Consultant Service LLC Repräsentanzbüro

Address: Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 19th May, 2020 until 25th May, 2024.

Authorized by:

Signature

General manager

Place: Guangdong, China

CHEN APO LINE

Date: 2020.05.19

 ϵ