Form QAT_10-M04, version 00, effective since March 6th, 2020

(€ Documentation Review

No. 0H200325M.NCM0235



Co., Ltd.

RM 606, No. 312, Lane 645, Renmin RD. Ningbo,

Zhejiang. P.R. China

Review goal: Verification of the presence of Technical

Documentation compatible with the Medical Devices Directive 93/42/EEC

Annex VII

Product: Disposable Surgical Mask (Not Sterile)

Model(s): 175mm x 95 mm, 145 mm x 95 mm

Classification: Class I (Not Sterile)

(accordingly to the Manufacturer's declaration)

Review output:

This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European

Standard for Medical Devices.

The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3

available at: www.entecerma.it

Date of issue 25 March 2020
Approver
ECM Service Director
Luca Redonni

Expiry date 24 March 2025

Technical Expert
Amand