

3-layered Surgical disposable protective mask (Not Sterile)

Company Profile:

DIMS Biotechnology Co., Ltd.

Manufactured:

China

Official Website:

<https://hndims.com/index.php?r=frontend/index/index>

Certification:

CE

MOQ:

100000 up

Certification

Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

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

CE Documentation Review



No. 3J200322.HDBUO97

Holder:

Hunan DIMS Biotechnology Co., Ltd.
609/603, 604, 607, 608 and 609, Science and
Research Building, No. 229 Tongzi Po West Road,
Changsha High-tech Development Zone,
Changsha, Hunan

Review goal:

Verification of the presence of Technical
Documentation compatible with the
Medical Devices Directive 93/42/EEC
Annex VII

Product:

Surgical mask (Not Sterile)

Model(s):

17.5cm×9.5cm, 14.5cm×9.5cm,
12.5cm×9.5cm, 12cm×7cm

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 22 March 2020

Approver
ECM Service Director
Luca Redonni

Expiry date 21 March 2025

Technical Expert
Amanda Biondi

Ente Certificazione Macchine

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Testing report from China

湖南省药品检验研究院 (湖南药用辅料检验检测中心) 检测报告书



报告编号: FY202040483

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样品名称	一次性使用医用口罩(非灭菌)	样品编号	FY202040483
生产单位/产地	湖南迪斯生物技术股份有限公司	批号/生产日期	20200224
剂型/类别	其他	规格/级别	平面耳挂式 17.5cm×9.5cm
检验目的	委托检验	包装规格	10枚/袋
检验项目	单项检验	有效期至/有效期	3年
收样日期	2020-02-26	样品数量	30个
抽样单位/供样单位	湖南迪斯生物技术股份有限公司		
被抽样单位	/		
检验依据	YY/T 0969-2013 一次性使用医用口罩		
检验项目	标准规定	检验结果	
4.5细菌过滤效率(BFE)	应不小于95%	99.9%	
以下空白			
备注: /			
结论: 本品按供样单位要求, 参照YY/T 0969-2013一次性使用医用口罩检验上述项目, 结果如上。			
授权签字人	李长喜	签发日期	2020-03-02