

常州市回春医疗器材有限公司
CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

DECLARATION OF CONFORMITY

Manufacturer: Changzhou Huichun Medical Equipment Co.,Ltd.
Address: Sanhekou, Zhenglu Town
213115Changzhou,Jiangsu
PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp.GmbH(Europe)
Address: EiffestraBe 80, 20537 Hamburg, GERMANY

Products: SURGICAL MASK WITH EARLOOP
Batch no : 20200808
Classification: (MDD Annex IX): I non sterile
Conformity Assesment Route : Annex VII
Classification: (EN 14683 + AC:2019) : Type II

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC, EN 13483 + AC:2019). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer and the notify body.

DIRECTIVES

General Applicable Directive

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC)

Standard:

All applicable harmonized standard (published in the Official Journal of the European Community).

EU Notification number:

DE/CA05/MP-238321-2570-00, 14.04.2020,
GERMANY

Competent Authority: BGV Germany

Date: 2020-08-08

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Test Report

According to: EN 14683:2019 +AC : 2019

Product Name	SURGICAL MASK WITH EARLOOP		
BATCH NO.	20200808	Report NO.	20200808
MFG. DATE	2020-08-08	Spec.	Class I nonsterile, Type II
EXP. DATE	2025-08-08	Test Dates	2020\08\15
QTY	1680000 pcs	Report Dates	2020\08\15

Inspection items	Guideline / Result	Conclusion
Package	Box package	Passed
Material	PP nonwoven, filter GSM : 25+25+25	Passed
Irritability Test	No irritability	Passed
Bacterial filtration efficiency Test (BFE)	98,3%	>98% Passed
Differential Pressure Test	37.2 Pa/cm2	<40 Pa/cm2 Passed
Microbial Cleanliness Test	2-7 CFU/g	<30 CFU/g Passed

Conclusion: Products evaluation is according to EN 14683:2019 +AC : 2019.
Batch have passed Quality Inspection.

Inspector: Lu Xiangxiu

Review: Zhu Xiaofeng

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