

常州市回春医疗器材有限公司

CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

Test Report

According to: EN 14683:2019 +AC : 2019

Product Name	SURGICAL MASK WITH EARLOOP		
BATCH NO.	20200602	Report NO.	20200602-1
MFG. DATE	2020-06-02	Spec.	Class I nonsterile, Type II
EXP. DATE	2025-06-02	Test Dates	2020\06\02
QTY	700000 pcs	Report Dates	2020\06\02

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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李国兴

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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 : 20200602

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: 2020-06-02

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蔡国梁

PROPUNERE TEHNICA

MASTI 3 STRATURI/ MASTI CHIRURGICALE DE UNICA FOLOSINTA, Masti chirurgicale de uz medical, dispozitive medicale clasa I, tip II

- Masti chirurgicale cu 3 straturi si 3 pliuri, 2 straturi exterioare din material netesut, un strat interior din material filtrant
- Mastile sunt prevazute cu lamela nazala si prindere cu elastic
- Confectionate din material netesut hipoalergenic
- Culoare: albastru
- produs nesteril
- produsul asigura protectie si filtrare bacteriana mai mare de 98%, BFE>98
- ambalare 50 bucati/cutie
- termen de valabilitate: 5 ani
- dispozitiv medical clasa I nesteril, in conformitate cu Directiva Europeana 93/42, masca chirurgicala tip II, conform SR EN 14683+AC:2019,
- Straturile exterioare din material netesut rezistent la manevrele din timpul utilizarii; intre acestea se gaseste positionat un strat interior din material filtrant (meltblown, rezultat din polipropilena).
- Masca are un design anatomic pentru a acoperi cat mai bine gura, nasul si obrazii, aceasta se fixeaza cu legaturile elastice din spatele urechilor si prin presarea benzii transversale flexibile pe forma nasului, conform instructiunilor de utilizare. Forma dreptunghiulara, dimensiune aproximativ 17.5x9.5cm.
- Produsul respecta in totalitate standardul SR EN 14683+AC:2019, conform buletin de Analiza.
- Produsele oferite sunt noi, nefolosite
- Etichetarea si marcarea ambalajului, cf pct 13 din Anexa 1 la Directiva Europeana 93/42, (transpuse in HG 54/2009, anexa 1 din HG55/2009 sau anexa 1 din HG 798/2003)
- Producator: Changzhou Huichun Medical Equipments Co., Ltd, China

SC ROVAL MED SRL

