### 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:

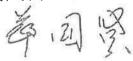
DE/CA05/MP-238321-2570-00, 14.04.2020,

**GERMANY** 

Competent Authority: BGV Germany

Date: 2020-08-08

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# 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	GICAL 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

常州市回春医疗器材有限公司CMI2200 NLCETTE CAPIFOT OLD

奉回紧