

SCHEDA TECNICA

15037

Colore azzurro

CAMICE VISITATORI in T.N.T.

composto da:

- Camice in TNT SPUNDBOND 30 gr
- colore: azzurro
- chiusura con lacci posteriori e sul collo regolabili;
- polsini in maglina



DESCRIZIONE GENERALE	CAMICE VISITATORE
Colori disponibili	azzurro
Taglia	Unica
Misure	Larghezza manica 27.0 cm Lunghezza manica 62.0 cm (compreso polsino in maglina) Larghezza camice 68.0 cm Lunghezza camice 119.5 cm
Confezione	Singolarmente imbustati. Misure busta: 35 x 30 cm
Imballo	Cartone da 100 PEZZI (dimensioni 54x25x21 cm)
Peso imballo	8 kg
Destinazione d'uso	Dispositivo di Protezione Individuale (D.P.I) di I categoria, solo per rischi minimi.
Certificazioni	EN 14605 dichiarazione CE Rappresentante autorizzato Europeo: Caretechion GmbH, Niederrheinstr 71, 40474 Duesseldorf, Germany
Avvertenze per l'uso e lo stoccaggio	- Abbigliamento monouso non sterile adatto ai visitatori, per rispettare le regole di igiene e da utilizzarsi sopra all'abbigliamento. - Articolo da non utilizzare al di fuori del campo di applicazione definito. - Conservare l'abbigliamento nel proprio imballaggio originale in luogo fresco ed asciutto. - Conservare la confezione per eventuali richieste di informazioni e garantire la rintracciabilità del prodotto. - Effettuare sempre una prova preliminare nelle reali condizioni di utilizzo
<i>allegato</i>	Certificazione conformità materiale di produzione
<i>produttore</i>	Xiangxi Huikang MEDical Device Co.Ltd, 2,3nd floor, B building, GuangZhou Industrial Park. XiangXi Economic Development District, HuNan Province, PRC
<i>Distributore Italia</i>	Medical Group S.r.l. Corso re Umberto 82, 10128 Torino

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: /

Xiangxi Huikang Medical Device Co.,Ltd
2-3nd Floor, B Building, GuangZhou Industrial Park,
XiangXi Economic Development District, HuNan Province,
PRC

EC Authorized Representative:/

Caretechion GmbH
Niederrheinstr 71,40474 Duesseldorf, Germany

We declare under our sole responsibility that:

Name of the medical device: /

Disposable Isolation Gown

Product code:/

UMDNS code 15037 (Gowns, Isolation)

Intended purpose: /

The Disposable Isolation Gown is intended to be worn by healthcare providers or visitors to isolate themselves from patients. The isolation gown helps to protect the patient from the transfer of infectious agents carried by the healthcare provider or visitor.

Basic UDI-DI:/

NA

Trade name:/

None

of class: /

Rule1, Class I
according to annex VIII of Regulation (EU) 2017/745 /

CS reference: /

NONE

Conformity assessment: /

Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 /
according to Article 52(7) of Regulation (EU) 2017/745 /

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Hunan Province, China

Ort, Datum / Place, date /
Lieu, date / Luogo, data

June 17, 2020

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



MEDICAL GROUP SRL
C.so Re Umberto 82 - 10128 Torino
P.Iva 06554720018

TEST REPORT

(Electronic version)



No:200375902

VERIFICATION WEBSITE: www.gtcc.net.cn

VERIFICATION CODE: QSQM-3640-34

ISSUE DATE:2020-12-02

扫码下载报告



APPLICANT: XIANGXI HUIKANG MEDICAL DEVICE CO.,LTD
ADDRESS: 2ND FLOOR , B BUILDING, GUANGZHOU INDUSTRIAL PARK , XIANGXI ECONOMIC DEVELOPMENT DISTRICT, HUNAN PROVINCE , PRC

INFORMATION CONFIRMED BY APPLICANT:

DISPOSABLE ISOLATION GOWN

QUANTITY: 1 PIECE

MANUFACTURE'S NAME: XIANGXI HUIKANG MEDICAL DEVICE CO.,LTD

STANDARD ADOPTED:

GB 15979-2002 <Hygienic standard for disposable sanitary products>

DATE RECEIVED/DATE TEST STARTED: 2020-12-02

CONCLUSION:

COLIFORM GROUP	M
TOTAL AMOUNT OF BACTERIAL COLONY	M
TOTAL AMOUNT OF FUNGUS COLONY	M
PSEUDOMONAS AERUGINOSA	M
STAPHYLOCOCCUS AUREUS	M
HEMOLYTIC STREPTOCOCCUS	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"___" -NO COMMENT

REMARK:

THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200368946.

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

THE EXPERIMENT WAS CARRIED OUT AT No. 1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

APPROVED BY:

ZiShan Guo SENIOR ENGINEER

郭子山



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COLIFORM GROUP (GB 15979-2002 ANNEX B)			M
	NOT DETECTED	REQUIREMENT MUST NOT BE DETECTED (GB 15979-2002)	
TOTAL AMOUNT OF BACTERIAL COLONY (CFU/g) (GB 15979-2002 ANNEX B)			M
	80	REQUIREMENT ≤200 (GB 15979-2002)	
TOTAL AMOUNT OF FUNGUS COLONY (CFU/g) (GB 15979-2002 ANNEX B)			M
	40	REQUIREMENT ≤100 (GB 15979-2002)	
PSEUDOMONAS AERUGINOSA (GB 15979-2002 ANNEX B)			M
	NOT DETECTED	REQUIREMENT MUST NOT BE DETECTED (GB 15979-2002)	
STAPHYLOCOCCUS AUREUS (GB 15979-2002 ANNEX B)			M
	NOT DETECTED	REQUIREMENT MUST NOT BE DETECTED (GB 15979-2002)	
HEMOLYTIC STREPTOCOCCUS (GB 15979-2002 ANNEX B)			M
	NOT DETECTED	REQUIREMENT MUST NOT BE DETECTED (GB 15979-2002)	



—End of Report—

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