

Technical Sheet

Product: Disposable shoe covers 100 pcs.

Manufacturer: Hubei Ingenuity Medical

EC REP: MedPath GmbH



Product Description

- The disposable shoe covers are ideal for use in medical clinics, laboratories and hospitals.
- Dust-resistant, waterproof and non-slippery product
- Antibacterial protection
- The shoe covers are classified as class I under MDR under EN 13688:2013

Technical specifications

Material	CPE (Chlorinated Polyethylene)
Color	Blue
Size	15 x 41 cm
Thickness	15 µm
Weight	3 g ± 0.2
Waterproof	Yes
Antibacterial	Yes
Packaging	1 bsx = 40 sets x 100 pcs.
Medical Device	Yes



EU DECLARATION OF CONFORMITY
According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Hubei Ingenuity Medical Products Co., Ltd.
No. 1 West of Industrial Park Road, Yanglinwei Town,
433000 Xiantao City, Hubei Province, China

Trademark: 

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: Not available yet

Trade name: Shoe covers

Product Name: Shoe covers

Product code / Catalogue number: INM-SC 101, INM-SC 201

Basic UDI: 697442339

Classification acc. to MDR Ax. VIII: Class I, rule I

Applied Standard & Common Specification: EN 13688:2013 EN ISO 14971:2012 EN 1041:2013
EN ISO 15223-1:2016 EN ISO 10993-10:2013
EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009

Conformity assessment procedure: Annex II + Annex III of MDR

Registration number: DE/CA61/00167703

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.

Signature: 
Yu Fu

General Manager: Xiantao, 21. 09. 2020



Hubei Ingenuity Medical Products Co., Ltd.

TEST REPORT

Report No.:INM2022051701

Item:CPE Shoe Cover

Size: 15*41cm 3g

LOT: 220415

Test Date: 20220517

Kind of inspection: Sample inspection of qualified products before delivery

Test Department: Quality Inspection Department (outsourced laboratory)

Sample Qty: 1000pcs

Sampling basic number: 100000pcs

Test standard: 《GB/T 24218.3- 2010 National Standard Textile

Nonwovens Test Method Part 3》、《YY/T 1633-2019 Disposable medical protective shoe cover》、《GB 15979- 2002 National Standard Hygienic standard for disposable sanitary articles》



Hubei Ingenuity Medical Products Co., Ltd.

No.	Test items	Unit	Technical requirements clause	Test Method	Test Results	Conclusion
1	Appearance	/	The protective shoe cover should be free of mildew, and the surface should not have defects such as impurities, adhesion, cracks, and breakage. The connection part of the shoe cover should be flat and tight.	YY/T 1642-2019	Meet the requirements	qualified
2	Construction and Specification	/	Protective shoe covers should be sized to cover the user's feet and legs. Specifications and dimensions should conform to the design dimensions of the logo, tolerance: ±10% The structure of the protective shoe cover should be reasonable and easy to put on and take off. The protective shoe cover should be designed with a closure, which can be closed by elastic closure, drawstring closure or strapping.	YY/T 1642-2019	Meet the requirements	qualified
3	Weight	(g)	3±0.2 (Tolerance: ±10%)	Average 2.86	Meet the requirements	qualified
4	Thickness	(mm)	≥ 0.01	Average 0.015	Meet the requirements	qualified
5	Water impermeability	(kPa)	≥ 1.67	Average 20.4	Meet the requirements	qualified



Hubei Ingenuity Medical Products Co., Ltd.

6	Surface moisture resistance		≥ 2	Average 4-5	Meet the requirements	qualified
4	The total number of bacterial colonies	cfu/g	≤20	GB 15979-2002 Appendix B	<20	qualified
5	coliform bacteria	cfu/g	not checked out	GB 15979-2002 Appendix B	not checked out	qualified
6	Pseudomonas aeruginosa	cfu/g	not checked out	GB 15979-2002 Appendix B	not checked out	qualified
7	Staphylococcus aureus	cfu/g	not checked out	GB 15979-2002 Appendix B	not checked out	qualified
8	hemolytic streptococcus	cfu/g	not checked out	GB 15979-2002 Appendix B	not checked out	qualified
9	total number of fungal colonies	cfu/g	≤100	GB 15979-2002 Appendix B	<20	qualified



ANEXA din data 09.06.2021
LA AVIZUL DE FUNCȚIONARE
Nr. 7111/19.08.2020 al MEDPLAZA HEALTH SRL

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată și în baza documentației înaintate, Avizul de funcționare nr. 7111/19.08.2020 se completează după cum urmează:

Unitatea este distribuitor al producătorilor:

Nume productor	Tara
IM DEUTSCHLAND GMBH	GERMANIA
ALCON LIFE SCIENCES	INDIA
ALCON MEDICAL SPAIN S.A.	SPAIN
ANG SPONG INDUSTRIAL CO.LTD	CHINA
BEIJING PERLONG NEW TECHNOLOGY CO.LTD	CHINA
BEIJING BEIER BIOENGINEERING CO.LTD	CHINA
BEIJING LEPID MEDICAL TECHNOLOGY CO.LTD	CHINA
CHANGZHOU HIR ANGIOMA MEDICAL DEVICES CO.LTD	CHINA
C.A. DENTAL IND.CO. LTD	GREECE
CRISTINE / WIAZZERENT GMBH + CO KG	GERMANIA
COMFORT RUBBER GLOVES INDUSTRIES SON S&B	MALAYSIA
CRANBERT SON S&B	MALAYSIA
ECYBER SON S&B	MALAYSIA
ECULAR DEUTSCHLAND GMBH	GERMANIA
ELIMONDA SPA	ITALY
FELTERSTEN GMBH	GERMANIA
JALIN WOODPECKER MEDICAL INSTRUMENT CO.LTD	CHINA
HAIJIAN MEDICALIZE CO.LTD	CHINA
HANGZHOU REALITY TECH CO. LTD	CHINA
HEFELI C & P NONWOVEN PRODUCTS CO.LTD	CHINA
HE CARE THAI GLOVES CO.LTD	THAILAND
HUIJIAN CITY HENGCHEN MEDICAL PRODUCT CO.LTD	CHINA
HUIJIAN TIANDI MEDICAL INSTRUMENTS CO.LTD	CHINA

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MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
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Numa producer	Tara
HUBEI INGENUITY MEDICAL PRODUCTS CO.,LTD.	CHINA
HUBEI YU MING PROTECTIVE PRODUCTS CO., LTD	CHINA
HVCARE INTERNATIONAL CO.,LTD	TAIWAN
JOINTAIR BIOMEDICAL TECHNOLOGY CO.,LTD	CHINA
LIANHUI FANSHI MASKS FACTORY	CHINA
MASTER GLOVE MANUFACTURING NON-BED	NEALAFZSA
MEDIMPPT BP, ZIGU	POLAND
MELAG MEDIZINTECHNIK GMBH & CO. KG	GERMANY
MELPO INTERNATIONAL INC.	U.S.A
NANJING YAZHIME MEDICAL TECHNOLOGY CO., LTD	CHINA
NINGBO JCAN MACHINES CO.,LTD	CHINA
NINGBO JIANGHAI WOMEN MEDICAL INSTRUMENT CO.,LTD	CHINA
ORO CLEAN CHEMIE AG	ITALY
PT. MEDHAFI TECHNOLOGIES	INDONESIA
PT. UNIVERSAL GLOVES	INDONESIA
QINGDAO HIGATUP BIOTECH CO., LTD.	CHINA
SC. TAINIS CONCEPT SRL	ROMANIA
SCHULZE & MAYR GMBH	GERMANY
SECAN LTD	CANADA
SEMPERIT INVESTMENTS ASIA PTE LTD	SINGAPORE
SEPPICONT	FRANCE
SHANGHAI IVEN MEDICAL TECHNOLOGY CO., LTD	CHINA
SHANGHAI RITE CROWN INDUSTRY CO.,LTD	CHINA
SHENZHEN IMOE MEDICAL TECHNOLOGY CO.,LTD	CHINA
SHENZHEN MEDIRINA BIOTECH CO., LTD	CHINA
SIBOMA DENTAL A/S	DANEMARK
SMART GLOVE CORPORATION NON-BED	NEALAFZSA
SME AG	NELOIA
SPORA DENTAL A/S	REP. CHINA
TECHNOAR SPA	ITALY
TIG MEDICAL NON-BED	NEALAFZSA
TRIDENT DENTAL PRODUCTS CO.,LTD	CHINA
TURKAL SAĞLIK HAYATLARI MEDICAL TEKNIK SANAYI VE TİC. AŞ	TURKEY
VOKIT MEDICAL VERTRIEB GMBH	GERMANY
WUHAN HUAJIN NON-BED CO., LTD	CHINA
WUHAN JIANGHAI MEDICAL MATERIAL CO., LTD	CHINA
WUJIAN HUI MEDICAL ARTICLES CO., LTD	CHINA
ZHANGJIANG STAR ENTERPRISE CO.,LTD	CHINA

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Nume producator	Tara
FARMACE SPA	ITALIA

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE
Agencia Națională a Medicamentului și a
Dispozitivelor Medicale din România
Roxana Stefania STROE



Pagina 3 de la Anexa din 09.06.2021 de la Avizul de functionare nr. 7111/19.08.2020

Thank you!



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