FISA TEHNICA PRODUS

Denumire Produs: Set 50 Masti Medicale IIR 4 straturi Serix portocaliu/mov/negru/rosu/albastru/verde
Producator: Hubei Ingenuity
EC REP: MedPath GmbH

1. DESCRIERE

Set 50 Masti Medicale 4 Straturi Tip IIR SERIX
Editie Premium | Protectie Ridicata | Full Color |

Caracteristici si avantaje:
•Masca medicala premium full colour (exterior, interior si bretele elastice)
•Clasificare: Tip IIR
•Eficienta Filtrare Bacteriana (BFE) ≥98%
•4 Straturi (PP + PP + Filtru + PP)
•Tija metalica nazala ajustabila
•Produs non-steril si de unica folosinta
•Conforma cu EN 14683 - 2019

Comparatie	**Tip IIR**	**Alte Masti**
Filtrare Bacteriana (BFE)	**≥98%**	≥95%
Respirabilitate (Pa/cm2)	**<60**	<40
Rezistenta la Stropire	**DA**	NU

Date tehnice:
•Culoare: rosu (red)
•Ambalare: 50 buc / cutie, 40 cutii / bax
•Dimensiune masca: 175 x 95 mm
•Dimensiune cutie: 192 x 100 x 80 mm
•Greutate masca: 3,64 g

Precautii:
•Inainte de utilizarea mastii, spalati-va pe maini cu dezinfectant pe baza de alcool,
• sau apa si sapun
•Evitati atingerea mastii in timpul purtarii
•Nu folositi masca daca cutia este grav deteriorata

Conditii de depozitare:
•Produsul trebuie depozitat intr-un spatiu inchis cu o umiditate relativa de sub 80%
•Evitati expunerea directa in soare a produsului
•Nu depozitati produsul langa substante toxice
•Pastrati produsul departe de substante inflamabile

Declaratie de conformitate (EN)

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, Yangliuwei Town, 433000 Xiantao City, Hubei Province, China
Trademark:	InMed Healthcare&PPE
SRN:	Not available yet
European Representative:	MedPath GmbH
	Mies-van-der-Rohe-Strasse 8
	80807 Munich, Germany
SRN:	Not available yet
Trade name:	Medical face mask
Product Name:	Disposable medical face mask
Product code / Catalogue number:	INM-3PM/4PM 17.5x9.5cm,14.5x9.5cm
Basic UDI:	697442339
Classification acc. to MDR Ax. VIII:	Class I, rule I
Applied Standard & Common Specification:	EN 14683:2019
Conformity assessment procedure:	Annex II + Annex III of MDR
Registration number:	DE/CA61/00167698

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

MedPath

EU- Compliance Review Certificate

Regulation (EU) 2017/745 on Medical Devices (MDR), Article 19
Class I non-sterile and without measuring function

No. A0476K001

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

Product Category(ies): See Appendix A

CE

This is to certify that, MedPath GmbH has verified the aforementioned manufacturer declares to conform with all applicable requirements set in the Medical Device Regulation (EU) 2017/745 for the product category(ies) listed in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Regulation.
When the manufacturer affixes CE mark to the product category(ies) listed above, it remains the manufacturer's responsibility to ensure continuous compliance with all applicable requirements of the aforementioned Regulation.

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

Issued Date: 2020-09-12 MedPath GmbH

Expiration Date: 2025-09-12

MedPath

Appendix A: Product Category(ies)

Name
Medical face mask
Surgical gown
Shoe covers
Sleeve covers
Caps
Scrub suit
Bed sheet
Colonoscopy pants

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

CE

MedPath GmbH · Mies-van-der-Rohe-Strasse 8 · 80807 Munich · Germany

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority

Code	DE/CA61
Bezeichnung / Name	Regierung von Oberbayern
Staat / State	Deutschland
Land / Federal state	Bayern
Ort / City	München
Postleitzahl / Postal code	80534
Straße, Haus-Nr. / Street, house no.	Maximilianstraße 39
Telefon / Phone	+49-89-21760
Telefax / Fax	+49-89-21762914
E-Mail / E-mail	medizinprodukteanzeigeverfahren@reg-ob.bayern.de

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority	Registriernummer / Registration number

Typ der Anzeige / Notification type
- ☒ Erstanzeige / Initial notification
- ☒ Änderungsanzeige / Notification of change
- ☒ Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG
- ☒ Hersteller / Manufacturer
- ☒ Bevollmächtigter / Authorised Representative
- ☒ Einführer / Importer
- ☒ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG
- ☒ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
  Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV
- ☒ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG
  Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

Anzeigender / Reporting organisation (person)

Code	DE/0000047823
Bezeichnung / Name	MedPath GmbH
Staat / State	Deutschland
Land / Federal state	Bayern
Ort / City	München
Postleitzahl / Postal code	80807
Straße, Haus-Nr. / Street, house no.	Mies-van-der-Rohe-Strasse 8
Telefon / Phone	089 189174474
Telefax / Fax	
E-Mail / E-mail	info@medpath.pro

Hersteller / Manufacturer

Bezeichnung / Name	Hubei Ingenuity Medical Products Co., Ltd.
Staat / State	CN
Ort / City	Xiantao City, Hubei Province
Postleitzahl / Postal code	433000
Straße, Haus-Nr. / Street, house no.	No. 1 West of Industrial Park Road, Yanglinwei Town
Telefon / Phone	+86-13607225191
Telefax / Fax	
E-Mail / E-mail	13607225191@126.com

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG

Bezeichnung / Name	Zheng Mei c/o MedPath GmbH
Staat / State	Deutschland
Land / Federal state	Bayern
Ort / City	München
Postleitzahl / Postal code	80807
Straße, Haus-Nr. / Street, house no.	Mies-van-der-Rohe-Strasse 8
Telefon / Phone	089 189174474
Telefax / Fax	089 5485 8884
E-Mail / E-mail	info@medpath.pro

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☒ I - steril / sterile ☒ I - mit Messfunktion / with measuring function ☒ I - steril und mit Messfunktion / sterile and with measuring function ☒ IIa ☒ IIb ☒ III ☒ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 ☒ Aktives implantierbares Medizinprodukt / Active implantable medical device ☒ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012
	App (Software auf mobilen Endgeräten) ☒ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Medical face mask**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **12-458**
	Nomenklaturbezeichnung / Nomenclature term **Maske, Chirurgie**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00017788

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
☒	Semikritische Medizinprodukte / Semicritical medical devices ☒ Gruppe A / Group A ☒ Gruppe B / Group B
☒	Kritische Medizinprodukte / Critical medical devices ☒ Gruppe A / Group A ☒ Gruppe B / Group B ☒ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☒ Dampfsterilisation / Steam sterilisation ☒ Gassterilisation / Gas sterilisation ☒ Strahlensterilisation / Radiation sterilisation ☒ andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **München**

Datum
Date **2020-10-13**

Name **Zheng Mei**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

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 producator	Tara
[illegible]	[illegible]

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Nume producator	Tara
HUBEI INGENUITY MEDICAL PRODUCTS CO.,LTD.	CHINA
[illegible]	[illegible]

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Nume producator	Tara
[illegible]	[illegible]

Prezentul document este valabil numai însoțit de avizul inițial.

PREȘEDINTE
Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
Roxana Ștefania STROE

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE/IEȘIRE
Ziua 10 Luna 06 Anul 2021

Către,

MEDPLAZA HEALTH SRL

Tel : 0737.552756

Prin prezenta vă înaintăm anexa avizului de funcționare aferentă cererilor cu numerele: DM 1974/22.03.2021 și DM 3475/21.05.2021.

Cu stimă,

PREȘEDINTE
Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
Roxana Ștefania STROE

Va multumim!

comenzi@medplaza.ro
office@medplaza.ro

www.medplaza.ro
0316.30.66.90