medcarehealthcare

EC DECLARATION OF CONFORMITY

MANUFACTURER : MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET A.Ş.

ADRESS : FATİH MAH. ÇAMLIK CAD.NO:54 35410 GAZİEMİR İZMİR /TÜRKİYE

PHONE : +90 232 2811617

PRODUCT : STERILE DISPOSABLE DRAPES

STERILE DISPOSABLE GOWNS

STERILE DISPOSABLE DRAPE PACKS

STERILE DISPOSABLE EQUIPMENT COVERS

(Product Details are at page 2 -4)

93/42/EEC, CONFORMITY ASSESSMENT ROUTE : ANNEX V

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF NAME OF THE MANUFACTURER.WE DECLARE THAT OUR PRODUCTS DO NOT CONTAIN HUMAN BLOOD DERIVATIVES, ANIMAL ORIGIN PRODUCTS AND DO NOT INCORPORATE A MEDICINAL SUBSTANCE, ANIMAL SKIN TISSUE OR BLOOD PRODUCT.

CLASSIFICATION : Class 1 Sterile

CLASSIFICATION RULE ACC.TO ANNEX IX 93/42/EEC: Rule 1

LOT NO : Starting with 20200410

NOTIFIED BODY : KiWA Belgelendirme Hizmetleri A.Ş.
ITOSB 9.Cadde No:15 Tepeören Tuzla-İstanbul TÜRKİYE

NOTIFIED BODY NO :1984

APPLICABLE STANDARDS:

EN ISO 13485:2016***+A11:2021***, EN ISO 14971:2019, EN ISO 11135: 2014***+A1:2019,*** EN 556-1:2001, EN ISO 15223-1:2021, EN ISO 11737-1:2018***+A1:2021,*** EN ISO 11737-2:2019, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN 17141:2020, EN ISO 10993-1:***2020***, EN ISO 10993-5 :2009, EN ISO 10993-7:2008+***A1:2019,*** EN ISO 10993-10:2010, EN 13795-1:2019, ***EN ISO 20417:2021***, EN ISO 11607-1:***2020***, EN ISO 11607-2:***2020***, EN 62366-1:2015

PRESERVATION PLACE OF DOCUMENT: Quality Management Department

PRESERVATION RESPONSIBILITY OF DOCUMENT: Quality Management Representative

DOCUMENT NO / REV.NO : KY-TF-002/***12***

REVISION DATE : ***26.07.2022***

CERTIFICATE NO / *DATE* : 1984-MDD-20-649 / 08.04.2020

VALIDITY OF CERTIFICATE : 27.05.2024

SIGNATURE : Mehmet Demir

General Manager

Digitally signed by Cojocaru Vera
Date: 2025.06.06 21:29:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

MEDCARE SAĞLIK ÜRÜNLERİ SAN.VE TİC.A.Ş.
Fatih Mahallesi Çamlık Caddesi No: 54 35414
Gaziemir / İZMİR

medcarehealthcare

PRODUCT NAME	GMDN CODE	REFERENCE CODE INTERVAL
STERILE DISPOSABLE DRAPE PACKS		
General Surgery Drape Pack	47783	110.001.01-113.001.01
Split Drape Pack	47783	114.001.01-114.031.01
Laparotomy Drape Pack	47783	115.001.01-115.200.01
Laparoscopy Drape Pack	47783	116.001.01-116.200.01
ENT Drape Pack	47783	117.001.01-117.031.01
Cardiovascular Drape Pack	47783	130.001.01-130.200.01
Angiography Drape Pack	47783	132.001.01-132.155.01 132.200.01-132.500.01
Pacemaker Drape Pack	47783	132.156.01-132.199.01
Craniotomy Drape Pack	47783	140.001.01-140.100.01
Neurosurgery Drape Pack	47783	140.101.01-140.200.01
Laminectomy (Vertebra) Drape Pack	47783	141.001.01-141.031.01
Arthroscopy Drape Pack	47783	150.001.01-150.250.01
Shoulder Arthroscopy Drape Pack	47783	151.001.01-151.120.01
Extremity Drape Pack	47783	152.001.01-152.120.01
Hip Drape Pack	47783	153.001.01-153.200.01
Lateral Hip Pack	47783	154.001.01-154.011.01
Hand Pack	47783	155.001.01-155.011.01
Delivery Drape Pack	47783	160.001.01-160.200.01
Ceaserean Drape Pack	47783	161.001.01-161.250.01
Gyneocology Drape Pack	47783	162.001.01-162.051.01
O.P.U Pack	47783	163.001.01
Urology Pack	47783	170.001.01-170.031.01
Tur Drape Pack	47783	171.001.01-171.150.01
Cystoscopy Drape Pack	47783	172.001.01-172.031.01
Percutanous Drape Pack	47783	173.001.01-173.150.01
Opthalmic Drape Pack	47783	181.001.01-181.150.01
Opthalmic Pack-B	47783	182.001.01
Minor Surgery Drape Pack	47783	101.001.01-101.101.01
STERILE DISPOSABLE DRAPES		
Laparotomy Drape	47783	225.001.01-225.031.01
Laparoscopy Drape	47783	226.001.01-226.031.01
Cardiovascular Drape	47783	230.001.01-230.051.01
Angiography Drape	47783	232.001.01-232.153.01
Pacemaker Drape	47783	232.154.01-232.184.01
Craniotomy Drape	47783	240.001.01-240.031.01
Laminectomy (Vertebra) Drape	47783	241.001.01-241.031.01
Arthroscopy Drape	47783	250.001.01-250.051.01
Extremity Drape	47783	252.001.01-252.031.01
Hand Drape	47783	255.001.01-255.011.01

Vertical Isolation Drape	47783	259.001.01-259.031.01
Caesarean Drape	47783	261.001.01-261.052.01
Gynaecology Drape	47783	262.001.01-262.051.01
O.P.U Drape	47783	263.001.01
Underbuttocks Drape	47783	269.001.01-269.031.01
Urology Drape	47783	270.001.01-270.031.01
T.U.R. Drape	47783	271.001.01-271.031.01
Cystoscopy Drape	47783	272.001.01-272.031.01
Percutanous (PCNL) Drape	47783	273.001.01-273.031.01
Ophthalmic Drape	46697	281.001.01-281.033.01
Plain Drape	47783	301.001.01-390.001.01 301.002.01-390.002.01
Adhesive Drape	47783	301.011.01-390.011.01
Fenestrated Drape	47783	301.031.01-390.033.01 305.041.01-335.041.01
Hip Drape(U Split Drape)	47783	301.021.01-390.021.01
Lateral Hip Drape	47783	342.021.01-342.031.01
Transparent Drape	47783	320.002.01-320.022.01
Back Table Cover	47783	701.001.01-709.001.01
Mayo Table (Stand) Cover	47783	710.001.01-711.001.01
Leg Drape(Leggings)	47783	780.001.01-784.001.01
Stockinette	47783	786.001.01-789.001.01
Baby Drape	47783	794.001.01-795.001.01
Nonwoven Tape Drape	47783	799.001.01
STERILE DISPOSABLE GOWNS		
Surgical Gown, Size S Surgical Gown, Size M Surgical Gown, Size L Surgical Gown, Size XL Surgical Gown, Size XXL Surgical Gown, Size XXXL	35778	10.001.01, 11.001.01, 13.001.01 10.002.01, 11.002.01, 13.002.01 10.003.01, 11.003.01, 13.003.01 10.004.01, 11.004.01, 13.004.01 10.005.01, 11.005.01, 13.005.01 10.006.01, 11.006.01, 13.006.01
Reinforced Surgical Gown, Size S Reinforced Surgical Gown, Size M Reinforced Surgical Gown, Size L Reinforced Surgical Gown, Size XL Reinforced Surgical Gown, Size XXL Reinforced Surgical Gown, Size XXXL	35778	20.001.01, 21.001.01, 22.001.01 20.002.01, 21.002.01, 22.002.01 20.003.01, 21.003.01, 22.003.01 20.004.01, 21.004.01, 22.004.01 20.005.01, 21.005.01, 22.005.01 20.006.01, 21.006.01, 22.006.01
Laminated Surgical Gown, Size S Laminated Surgical Gown, Size M Laminated Surgical Gown, Size L Laminated Surgical Gown, Size XL Laminated Surgical Gown, Size XXL Laminated Surgical Gown, Size XXXL	35778	40.001.01, 41.001.01 40.002.01, 41.002.01 40.003.01, 41.003.01 40.004.01, 41.004.01 40.005.01, 41.005.01 40.006.01, 41.006.01

Urology Gown, Size: L Urology Gown, Size: XL	35778	70.001.01 70.002.01
Full Protection Gown, Size L Full Protection Gown, Size XL	35778	80.001.01 80.002.01
Spunlace Surgical Gown, Size S Spunlace Surgical Gown, Size M Spunlace Surgical Gown, Size L Spunlace Surgical Gown, Size XL Spunlace Surgical Gown, Size XXL Spunlace Surgical Gown, Size XXXL	35778	91.001.01 91.002.01 91.003.01 91.004.01 91.005.01 91.006.01
Triplex Surgical Gown, S Beden Triplex Surgical Gown, M Beden Triplex Surgical Gown, L Beden Triplex Surgical Gown, XL Beden Triplex Surgical Gown, XXL Beden Triplex Surgical Gown, XXXL Beden	35778	87.001.01, 88.001.01, 89.001.01 87.002.01, 88.002.01, 89.002.01 87.003.01, 88.003.01, 89.002.01 87.004.01, 88.004.01, 89.002.01 87.005.01, 88.005.01, 89.002.01 87.006.01, 88.006.01, 89.002.01
STERILE DISPOSABLE EQUIPMENT COVERS		
Diatermy Bag, 33x30cm Diatermy Bag, 44x27cm Diatermy Bag, 30x50cm Diatermy Bag, 50x50cm Diatermy Bag, 40x35cm Diatermy Bag, 40x75cm Diatermy Bag, 35x45cm	12535	721.099.01 722.099.01 723.099.01 724.099.01 725.099.01 726.099.01 727.099.01
Liquid Collection Pouch	12535	729.001.01-729.099.01
Fluoroscopy Cover, Size: 25x25cm Fluoroscopy Cover, Size: 45x45cm Fluoroscopy Cover, Size: 60x60cm Fluoroscopy Cover, Size: 80x80cm Fluoroscopy Cover, Size: 100x100cm Fluoroscopy Cover, Size: 120x120cm Fluoroscopy Cover, Size: 75x80cm Fluoroscopy Cover, Size: 85x110cm	12535	730.099.01 731.099.01 732.099.01 733.099.01 734.099.01 735.099.01 738.099.01 739.099.01
X-ray Casette Cover Size:50x50cm Film bag with cord fastener, 60x60cm	12535	736.099.01 737.099.01
Cardboard Camera Cover, Size:14x250cm	12535	740.099.01
Microscope Cover, Zeiss, Size: 115x210cm,65mm lens Microscope Cover, Zeiss, Size: 115x260cm,65mm lens Microscope Cover, Zeiss, Size: 115x300cm,65mm lens Microscope Cover, Leica, Size: 115x165cm,70mm lens Microscope Cover, Leica, Size: 115x260cm,70mm lens Microscope Cover, Leica, Size: 115x300cm,70mm lens	12535	750.090.01 750.091.01 750.092.01 750.093.01 750.094.01 750.095.01

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2023/12/20
CL1/V3

Esteemed

Medcare Saglik Urunleri San. ve Tic. A.S.
Fatih Mah. Camlik Cad. No:54 35414 Gaziemir/izmir TÜRKIYE

Notified Body Confirmation Letter Reference: CERBO0291222

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Medcare Saglik Urunleri San. ve Tic. A.S.
Fatih Mah. Camlik Cad. No:54 35414 Gaziemir/İzmir TÜRKIYE
SRN Number (if available): TR-MF-000023643

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.
Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 08/01/2024 07:29:08

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-	-	-	-
-	-	-	-

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Disposable Gowns -Standard Surgical Gown	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Gowns -Reinforced Surgical Gown	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Drapes (e.g. Laparotomy Drape)	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Drape Packs (e.g. General Surgery Drape Pack)	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Equipment Covers - Microscope cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Equipment Covers -Cardboard camera cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD	Certificate 1984-MDD-20-649;

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		■ Same □ Substitute	NB:Kiwa Belgelendirme Hizmetleri-1984
Sterile Disposable Equipment Covers -Fluoroscopy cover	Class I devices placed on the market in sterile condition	Identification of the corresponding device under MDD ■ Same □ Substitute	Certificate 1984-MDD-20-649; NB:Kiwa Belgelendirme Hizmetleri-1984

Confirmation Letter Revision History

Rev. *Rev.*	**Date** *Date*	**Action** *Azione*
00	2023/12/20	Initial issue: Sterile Disposable Gowns -Standard Surgical Gown, Sterile Disposable Gowns -Reinforced Surgical Gown, Sterile Disposable Drapes (e.g. Laparotomy Drape), Sterile Disposable Drape Packs (e.g. General Surgery Drape Pack), Sterile Disposable Equipment Covers - Microscope cover, Sterile Disposable Equipment Covers -Cardboard camera cover,

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111