

EC DECLARATION OF CONFORMITY

MANUFACTURER : MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET A.Ş.
ADRESS : FATİH MAH. ÇAMLIK CAD.NO:54 35414 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)

(EU) 2017/745, CONFORMITY ASSESSMENT ROUTE : ANNEX IX

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE **REGULATION (EU) 2017/745 ON MEDICAL DEVICES**. 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 VIII (EU) 2017/745 : 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, EN ISO 14971:2019, EN 13795-1:2019, EN ISO 11135:2014, EN 556-1:2001, EN ISO 15223-1:2021, EN ISO 11737-1:2018, EN ISO 11737-2:2020, 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, **EN ISO 10993-10:2010**, **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-002-1/8


REVISION DATE : 02.11.2022

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

VALIDITY OF CERTIFICATE : 27.05.2024

SIGNATURE : Mehmet Demir

General Manager


MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET A.Ş.
Fatih Mahallesi Çamlık Cad.No:54 35414
Gazîemir / İzmir / Türkiye
Tic. Sic. No: 272450
Vergi No: 3541400000

PRODUCT NAME	GMDN CODE	REFERENCE CODE INTERVAL
STERILE DISPOSABLE DRAPE PACKS		
General Surgery Drape Pack	47783	110.001.01-113.001.01, 110.206RE.01
Split Drape Pack	47783	114.001.01-114.031.01
Laparotomy Drape Pack	47783	115.001.01-115.108.01
Laparoscopy Drape Pack	47783	116.001.01- 116.031.01,116.104.01,116.104RE.01
ENT Drape Pack	47783	117.001.01-117.031.01
Cardiovascular Drape Pack	47783	130.001.01-130.051.01, 130.108.01,130.112.01, 130.114.01,130.200.01,130.126.01
Angiography Drape Pack	47783	132.001.01-132.155.01 132.030R.01,132.060.01,132.061R.01, 132.073R.01,132.203.01,132.206.01, 132.221.01,132.222.01,132.225.01, 132.241.01,132.242.01,132.243WR.01 132.244.01,132.246.01,132.285.01, 132.294.01,132.305.01,132.318.01, 132.323.01,132.324.01,132.325.01, 132.269R.01,132.333.01, 132.335.01
Stimulator Set	47783	132.322.01
Pacemaker Drape Pack	47783	132.156.01-132.186.01
Craniotomy Drape Pack	47783	140.001.01-140.031.01
Neurosurgery Drape Pack	47783	140.101.01-140.141.01
Laminectomy (Vertebra) Drape Pack	47783	141.001.01-141.031.01
Arthroscopy Drape Pack	47783	150.001.01-150.051.01, 150.120.01,150.121.01,150.120R.01, 150.201.01, 150.201R.01
Shoulder Arthroscopy Drape Pack	47783	151.001.01-151.051.01
Extremity Drape Pack	47783	152.001.01-152.031.01, 152.108.01,152.112.01
Hip Drape Pack	47783	153.001.01-153.031.01 153.119.01- 153.132.01
Lateral Hip Pack	47783	154.001.01-154.011.01
Hand Pack	47783	155.001.01-155.011.01
Delivery Drape Pack	47783	160.001.01-160.031.01 160.116.01,160.121.01, 160.124.01,160.126.01
Cesarean Drape Pack	47783	161.001.01-161.129.01, 161.123RE.01, 161.124R.01
Cesarean Set	47783	161.212.01
Gyneecology Drape Pack	47783	162.001.01-162.051.01
O.P.U Pack	47783	163.001.01
Urology Pack	47783	170.001.01-170.106.01
Tur Drape Pack	47783	171.001.01-171.031.01, 171.129.01-171.134.01

Cystoscopy Drape Pack	47783	172.001.01-172.031.01
Percutaneous Drape Pack	47783	173.001.01-173.031.01, 173.122.01,173.124.01
Ophthalmic Drape Pack	47783	181.001.01-181.011.01
Ophthalmic Pack-B	47783	182.001.01
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
Percutaneous (PCNL) Drape	47783	273.001.01-273.031.01
Ophthalmic Drape	46697	281.001.01-281.033.01
Plain Drape	47783	301.001.01-370.001.01 301.002.01-364.002.01
Adhesive Drape	47783	301.011.01-364.011.01
Fenestrated Drape	47783	301.031.01-327.031.01, 306.033.01 305.041.01-335.041.01
Hip Drape(U Split Drape)	47783	311.021.01-341.021.01
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
STERILE DISPOSABLE EQUIPMENT COVERS		
Diatermy bag, 30x32 cm Diatermy bag, 43x35 cm Diatermy bag, 33x30cm Diatermy bag, 44x27cm Diatermy bag, 30x50cm	12535	712.099.01 713.099.01 721.099.01 722.099.01 723.099.01
Liquid Collection Pouch	12535	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