EC DECLARATION OF CONFORMITY

Manufacturer : Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.
1142 sok. No:35 Fatih Mah. Sarnıç - İzmir / Turkey
Phone: +90 232 2816003 Fax: +90 232 2816648

Product(s) : Scopy Drape 60 (Ref:227 01)
Scopy Drape 90*130 (Ref:227 02)
Scopy Drape 70*80 (Ref:227 05)
Scopy Drape 65 (Ref:227 06)
Scopy Drape 55 (Ref:227 07)
C-Arm Cover with Clips(ICE8130)
C-Arm Cover with Clips (ICE8132)
C-Arm Cover with Clips (ICE8230)
C-Arm Cover with Clips (ICE8232)
C-Arm Cover with Clips (ICE8330)
C-Arm Cover with Clips (ICE8332)
C-Arm Uniprotection Cover L (ICE4405)

GMDN Code : 43970

Classification : Class I sterile (MDD 93/42/EEC and MDR (EU)2017/745)

Assessment Route : Annex V (MDD 93/42/EEC)

Classification Rule : Rule 1 (MDD 93/42/EEC and MDR (EU)2017/745)

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and other relative Medical Deivce Rgulation (EU)2017/745. All supporting documentation is retained under the premises of the manufacturer.

We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Standards :

TS EN 13795	ISO 10993-1,5,7,10	ISO 11140-1	EN ISO 13485
ISO 22610	ISO 11135	ISO 11607-1,2	ASTM F 88, 1886
EN 1041+A1	ISO 11138-1,2	ISO 11737-1,2	ISO 14971
ISO 80000-1	ISO 15223-1	ISO 868-5	EN ISO/IEC17025
TS 642 ISO 554	TS EN 1895/AC	ISO 14161	ISO 14644-1,2,3,4,5
TS EN 556-1/AC	ASTM F 1929, 1980		

Notified Body : Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- Istanbul-Turkey

Certification No : 1984-MDD-20-682 (MDD 93/42/EEC)

Certification Date : 13.07.2020

Place : Izmir/ Turkey

Date of Issue : 15.01.2018

Signature : Armağan Yalgın
(Quality Manager)

medbar
TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.
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