EC DECLARATION OF CONFORMITY

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

Intended Use : Camera covers are sterile medical devices used to keep the environment sterile by covering the video camera cable or probe in cases where operations will be performed with a video camera in a sterile environment in hospitals.

GMDN Code : 37450 - Camera cover, single-use
Classification : Class I sterile
Classification Route : Annex V
Classification Rule : Rule 1

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and relative Medical Device Regulations. 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 13795-1	TS EN ISO 15223-1	TS EN 1041	TS EN ISO 13485/AC
ASTM F 88, 1886, 1929, 1980	TS EN ISO 10993-1, 4, 5, 7, 10, 11,18	TS EN ISO 14644-1, 2, 3, 4, 5	TS EN ISO 11135
			TS EN 62366-1
TS EN ISO 11138-1, 2	TS EN ISO 11140-1	TS EN ISO 11607-1, 2	TS EN ISO 11737-1, 2
TS EN ISO 22610	TS EN 868-5	TS EN ISO 14971/D1	TS EN 1779/A1
TS EN ISO 14161	TS EN ISO 80369-7	TS EN 1895	

Notified Body Information : Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- Istanbul-Turkey
Certification No : 1984-MDD-20-682
Certification Date : 13.07.2020
Issue Place : Izmir/ Turkey
Issue Place : 13.07.2020
Signature : Armağan Yalgın
(Quality Management Rep.)

medbar
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Products:

Ref	Product Name
ICE4280	Closed System Camera Cover Telescopically Folded With Card Insert 18x250 cm
ICE4290	Closed System Camera Cover With Ring Insert 14x250cm