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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) : Karman Cannula Injector Single Valve (Manual Vacuum Aspirator) Procedure Pack (Ref. 209 01)

Karman Cannula Injector Double Valve (Manual Vacuum Aspirator) Procedure Pack (Ref. 209 02)

Karman Cannula Injector - S (Manual Vacuum Aspirator) Procedure Pack (Ref. 209 03)

GMDN Code : 43989

Classification : Class II a

Assessment Route : Annex II and Annex VII

Classification Rule : Rule 2

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC. 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 :

EN 556-1/AC:2009	TS EN 1618	TS EN ISO 10079-2, 3	ISO 11135
ISO 15223-1	TS 7557	ISO 10993-1,5,7,10	ISO 11138-1,2
TS EN 1041+A1	TS 7558	TS EN ISO 11140-1	ISO 11607-1,2
ISO 11737-1,2	ISO 13485	ISO 14644-1,2,3,4,5	ISO 14971:2012
TS EN 1779/A1	EN ISO 9001/AC	ISO 14161	TS EN 868-5
TS 642 ISO 554	TS EN 1895/AC	EN ISO/IEC17025	EN ISO/IEC17025

Notified Body : UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. (2292)
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Certification No : M.2016.106.7000

Certification Date : 03.10.2016

Place : Izmir/ Tukey

Date of Issue : 03.10.2016

Signature : Orkun Hiçyılmaz
(Mandate Manager)

medbar
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