

- 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)
Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya – Ankara / Turkey
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Certification No : M.2016.106.7000

Certification Date : 03.10.2016

Place : İzmir/ Tukey

Date of Issue : 03.10.2016

Signature : Orkun Hiçyılmaz

(Mandate Manager)

medbar®
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