

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) : Karmen Cannula No:3 (Ref:208 03)
Karmen Cannula No:4 (Ref:208 04)
Karmen Cannula No:5 (Ref:208 05)
Karmen Cannula No:6 (Ref:208 06)
Karmen Cannula No:7 (Ref:208 07)
Karmen Cannula No:8 (Ref:208 08)
Karmen Cannula No:9 (Ref:208 09)
Karmen Cannula No:10 (Ref:208 10)
Karmen Cannula No:12 (Ref:208 12)

GMDN Code : 32655

Classification : Class II a

Assessment Route : Annex II and Annex VII

Classification Rule : Rule 5

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 ISO 11138-1,2 ISO 11140-1
TS EN ISO 15223-1 ISO 10993-1,5,7,10 ISO 11607-1,2 ISO 9001/AC
EN 1041+A1 ISO 11135 ISO 11737-1,2 TS EN 868-5
ISO 13485 ISO 14644-1,2,3,4,5 ISO 80000-1 TS 642 ISO 554
ISO 14971:2012 TS EN 1779/A1 TS 6074
TS EN 1895/AC ISO 14161 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 : İzmir/ Tukey

Date of Issue : 03.10.2016

Signature : Orkun Hiçyılmaz

(Mandate Manager)

medbar®
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