Declaration of Conformity

Name and Address of 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

DECLARATION OF CONFORMITY

I, *Ömer Baran*, hereby declare that the below mentioned medical device-
(i) complies with all the requirements under the Act;
(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and
(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name: Emesis Bag
Specified name: Emesis Bag (Ref. No:228 02)
Brand/model: Medbar
Manufacturer: Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.
Country of origin: TURKEY
Manufacturing site: Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş, 1142 sok. No:35 İzmir / Turkey
Risk-based classification: Class I other (not sterile and measuring function)
Classification rule: Rule 1
GMDN code: 36258

(B) EN ISO 13485:2012 Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate: Trans Pacific Certification Limited
Certificate number: MD-0884
Issuance date: Feb. 24, 2017
Expiry date: Feb. 23, 2017

(C) Standards Applied

- *EN ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971: Medical devices - Application of risk management to medical device*
- *EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- *EN ISO 15223-1: Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements*
- *TS EN 1041+A1: Information supplied by the manufacturer of medical devices*

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 05. December.2017.
I fully understand and acknowledge that it is an offence under Section 76 of the Medical device Act 2012 [*Act 737*] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.
Authorised Signatory:

Ömer Baran/General Manager ,05.12.2017

Digitally signed by Bolea Petru
Date: 2023.09.17 16:48:05 EEST
Reason: MoldSign Signature
Location: Moldova