DECLARATION OF CONFORMITY

PLASTİ-MED Plastik Medikal Ürünleri San. Ve Tic. Ltd. Şti.

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Product : BACTERIAL FILTERs

Classification : Class IIA Rule 3 according to **MDD 93/42/EEC (2007/47/EC) Annex IX**

NOTIFIED BODY : Kiwa Belgelendirme Hizmetleri A.Ş. / İTOSB 9. Cad. No:15 Tepeören Tuzla İstanbul Türkiye Tel:+90 216 593 25 75 Fax: +090 216 593 25 74 **E-mail:** posta@meyer.gen.tr
NOTIFIED BODY NUMBER : 1984
CERTIFICATE NO : 1984-MDD-11-100
CERTIFICATION ROUTE : ANNEX 2 FULL QUALITY MANAGEMENT SYSTEM (EXCEPT FOR SECTION 4)

Products per Reference Codes:

REF NO	PRODUCT NAME	GMDN CODE	REF NO	PRODUCT NAME	GMDN CODE
140101	BACTERIAL FILTER	43987	140201	BACTERIAL FILTER - ELITE	43987
140110	BACTERIAL FILTER WITH HMEF FILTER	37597	140210	BACTERIAL FILTER WITH HMEF FILTER - ELITE	37597
140120	BACTERIAL FILTER WITH HME FILTER	37597	140220	BACTERIAL FILTER WITH HME FILTER - ELITE	37597
140130	HEPA FILTER	37597			

that the following described product in our delivered version complies with the appropriate basic safety and health requirements of the Medical Device Directive 93/42/EEC (2007/47/EC) based on its design and type, as brought into circulation by us. In case of alteration of the device, not agreed upon by us, this declaration will lose its validity.

General Applicable Directives
Medical device Directive 93/42/EEC (2007/47/EC)
Standards

TS EN ISO 10993-1:2011 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
TS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements s
TS EN ISO 14971:2012 Medical devices - Application of risk management to medical device
TS EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
TS EN ISO 11135-1:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.
TS EN ISO 14644-1:2016 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
TS EN 1041+A1:2014 Information supplied by the manufacturer of medical devices.
TS EN ISO 9360-1:2010 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml
TS EN ISO 5356-1:2015 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

Date of issue : 01.08.2006
Signature :

Name : Muammer BERKSÖZ
Position : General Manager

Digitally signed by Tutunaru Diana
Date: 2024.12.23 12:22:36 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ