DECLARATION OF CONFORMITY

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

ADRESS : **Plasti-med Plastik Medikal Ürünleri San. Ve Tic. Ltd. Şti.**
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Product : **BREATHING and ANESTHESIA CIRCUITS**
Classification : **Class II A Rule 2** according to **MDD 93/42/EEC (2007/47/EC) Annex IX**
NOTIFIED BODY : **Kiwa Certification Services Inc.**
İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul TÜRKİYE
Tel.: +90 216 593 25 75 Fax: +9O 216 5932574
Web: htpp://www.kiwa.com.tr E-mail: posta@meyer.gen.tr
NOTIFIED BODY NO : **1984**
CERTIFICATE NO : **1984-MDD-11-100**
CERTIFICATION ROUTE : **ANNEX 2 FULL QUALITY MANAGEMENT SYSTEM (Except for section 4)**
Products per Ref. Codes :

REF NO	PRODUCT NAME	GMDN	REF NO	PRODUCT NAME	GMDN
480 XXX	ANESTHESIA CIRCUIT -CORRUGATED	37704	480 XXXS	ANESTHESIA CIRCUIT –CORRUGATED	37704
481 XXX	ANESTHESIA CIRCUIT -SMOOTHBORE	37704	481 XXXS	ANESTHESIA CIRCUIT –SMOOTHBORE	37704
482 XXX	ANESTHESIA CIRCUIT - EXTENDABLE	37704	482 XXXS	ANESTHESIA CIRCUIT – EXTENDABLE	37704
483 XXX 484 XXX	BREATHING CIRCUIT - CORRUGATED	37706	483 XXXS 484 XXXS	BREATHING CIRCUIT – CORRUGATED	37706
485 XXX 486 XXX	BREATHING CIRCUIT - SMOOTHBORE	37706	485 XXXS 486 XXXS	BREATHING CIRCUIT – SMOOTHBORE	37706
487 XXX 488 XXX	BREATHING CIRCUIT - EXTENDABLE	37706	487 XXXS 488 XXXS	BREATHING CIRCUIT – EXTENDABLE	37706
489 XXX	BREATHING CIRCUIT- HEATED WIRE	37706	489 XXXS	BREATHING CIRCUIT- HEATED WIRE	37706
489 XXX	BREATHING CIRCUIT- IPPB	37706	489 XXXS	BREATHING CIRCUIT- IPPB	37706
489 XXX	BREATHING CIRCUIT- COAXIAL	37706	489 XXXS	BREATHING CIRCUIT- BAIN (COAXIAL)	37706
489 XXX	BREATHING CIRCUIT- TRANSPORT VENTILATOR CIRCUIT	37706	489 XXXS	BREATHING CIRCUIT- TRANSPORT VENTILATOR CIRCUIT	37706
489 XXX	BREATHING CIRCUIT-IPPB CLOSED SYSTEM	37706	489 XXXS	BREATHING CIRCUIT-IPPB CLOSED SYSTEM	37706
489 XXX	KATATER MOUNT	37706	489 XXXS	KATATER MOUNT	37706
489 601	BREATHING CIRCUIT-'T' TUBE CIRCUIT	37706	489 601S	BREATHING CIRCUIT-'T' TUBE CIRCUIT	37706
489 641	BREATHING INHALATION- THREATMENT CHAMBER	34838	489 641S	BREATHING INHALATION- THREATMENT CHAMBER	34838
48960101	BREATHING CIRCUIT T CONNECTOR	43435	48960101S	BREATHING CIRCUIT T CONNECTOR	43435

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)

RELEVANT STANDARDS

EVS EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

TS EN ISO 14971:2012 Medical devices - Application of risk management to medical device

EVS EN ISO 20417:2021 Medical devices:Information to be supplied by the manufacturer

EVS EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

TS EN ISO 11135:2014 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 5356-1:2015 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

TS EN ISO 5367:2015 Anaesthetic and respiratory equipment - Breathing sets and connectors

Issue Date : 01.08.2006

Digitally signed by Tutunaru Diana
Date: 2024.12.23 12:23:29 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Signature :
Name : Muammer BERKSÖZ
Position : General Manager