

DECLARATION OF CONFORMITY



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

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Web : [http:// www.plasti-med.com](http://www.plasti-med.com)
E-mail : info@plasti-med.com
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.
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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

TS EN ISO 15223-1:2016

- Part 1: General requirements s

TS EN ISO 14971:2012

TS EN 1041+A1:2014

EN ISO 11607-1:2017

systems and packaging systems

TS EN ISO 11135-1:2014

routine control of a sterilization process

TS EN ISO 5356-1:2015

TS EN ISO 5367:2015

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

Medical devices - Application of risk management to medical device

Information supplied by the manufacturer of medical devices.

Packaging for terminally sterilized medical devices - Part 1:Requirements for materials, sterile barrier

Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

Anaesthetic and respiratory equipment - Breathing sets and connectors

Issue Date : 01.08.2006

Signature

Name

Position

:
: Muammer BERKSÖZ
: General Manager