



CARATTERISTICHE GENERALI

Termometro clinico elettronico, con segnale acustico a seconda della temperatura misurata, display a cristalli liquidi, di facile utilizzo. Fornito di astuccio in plastica . Auto spegnimento

CARATTERISTICHE TECNICHE

Range::32.0°C~ 42.9°C

Precisione:±0.1°C tra i 35.5°C e i 42.0°C

±0.2°C sotto I 35.5°C e oltre i 42.0°C

Display: display a cristalli liquidi

Batteria: Una batteria da 1.5V (SR41, UCC 392 or LR41)

Consumo Batteria: 0.15 milliwatts in modalità misurazione

Durata Batteria: più di 200 ore in continuo utilizzo

Allarme: Durata segnale circa 10 sec. dopo l'avvenuta misurazione

Temperatura ambientale d'uso: 10°C~ 35°C

Umidità: 25%RH ~ 85%RH

Norma CE : Prodotto conforme alla CE 93/42 e al DL 24.2.97

Rev.2020



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 074897 0011 Rev. 02

Manufacturer:

**NINGBO HI-TECH UNICMED
IMP. & EXP. CO., LTD.**

11/F, GREEN TOWN LVYUAN TOWER
588 CANGHAI ROAD
315040 NINGBO
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Wound Drainage System With and without Trocar, Suction Catheters, Stomach Tubes, Oxygen Mask With Reservoir Bag, Nasal Cannula, Suction Connection Tube With Yankauer Handle, Nebulizer Mask, Blood Lancets, Simple Oxygen Mask, Disposable Surgical Blades(with and without handle), Digital Thermometers, C.P.R. Mask, Blood Pressure Monitors, Tracheal Tubes, Reinforced Endotracheal Tubes, Disposable Air Cushion Face Masks, Laryngeal Mask Devices, Sterile Latex Surgical Gloves, Vacuum Blood Collection Needles for Single use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH19635EXT01

Valid from: 2019-09-23

Valid until: 2024-05-26

Date, 2019-09-23

Stefan Preiß
Head of Certification/Notified Body



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EC Certificate

Production Quality Assurance System
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Facility(ies):

NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD.
11/F, GREEN TOWN LVYUAN TOWER, 588 CANGHAI ROAD,
315040 NINGBO, PEOPLE'S REPUBLIC OF CHINA



NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD

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E-mail: info@unicmed.com
www.unicmed.com*

EC Declaration of Conformity

Manufacturer: Ningbo Hi-tech Unimed Imp. & Exp. Co., Ltd
11/F, Green Town Lvyuan Tower, 588 Canghai Road, Ningbo,
China 315040
European Repre- Shanghai International Holding Corp. GmbH(Europe)
Sentative: Eiffestrasse 80, 20537, Hamburg, Germany

Product Name Digital Thermometers
UMDNS Code: 14-032
Classification (MDD, Annex IX): II a, rule 10
Conformity/ Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Directives

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).]

All applicable harmonized standard(published in the Official Journal of the European Communities)

Notify Body: TÜV Product Service GmbH
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123
(EC) Certificate(s): No.G2 074897 0011 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2019-09-23

Place, Date of Issue: Ningbo, 2021-02-01

Signature:

