Pharma [+]

[+] aid [+] nautic [+] med [+] sport

# GARZA IDROFILA STERILE





## CARATTERISTICHE GENERALI

Compresse di garza monouso sterili di puro cotone idrofilo , colore bianco candido, pretagliate e non piegate. Dispositivo di medicazione non invasivo a contatto con la cute lesa indicato per ogni tipo di medicazione sterile, destinato ad esser utilizzato come barriera meccanica per la compressione e l'assorbimento di essudati. Prodotto sterilizzato ad ossido di etilene in conformità alla UNI EN 550

## CARATTERISTICHE TECNICHE

Sterile: Si. Sterilizzazione ad ossido di etilene
Presenza di lattice: No

MISURE:
cod.**400025** cm 10x10x25
cod.**400024** cm 18x40
cod.**400050** cm 10x20
cod.**400049** cm 20x20

Prodotto conforme alla direttiva **MDR 745/2017**

*Rev.2022*

**PHARMAPIU'** srl tel. fax e-mail http
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

# EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 074897 0015 Rev. 01**

**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):**

**Gauze Swab, Non-woven Swab, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), First-aid-kit, Disposable Vaginal Speculums, Umbilical Cord Clamps, Rectal Tubes, Nelaton Catheters, Disposable Urine Drainage Bags, Paediatric Urine Collectors, Oropharyngeal Airways, Sterile Medical Dressing Boxes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. 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


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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**Facility(ies):**

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CANGHAI ROAD, 315040 NINGBO, PEOPLE'S
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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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*http://www.unicmed.com*

*Tel:+86-574-8764 1261/ 8764 0975 8764 0976/ 8764 2798*
*Fax:+86-574-8764 1260*
*E-mail:info@unicmed.com*


## Declaration of Conformity

**Manufacturer:**
Name: Ningbo Hi-Tech Unicmed Imp. & Exp. Co., Ltd.
Add:11/F, Green Town Lvyuan Tower, No.588 Canghai Road,Ningbo, China
**European Representative:**
Name: Shanghai International Holding Corp. GmbH(Europe)
Add: Eiffestrasse 80.20537 Hamburg, Germany

Product name: **Gauze Swab**

Product specification: 10x10cm, 10x20cm, 20x20cm, 18x40cm

Product classification: I Sterile

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): G2S 074897 0015 Rev. 01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2019-09-23

Place, Date of Issue: Ningbo, 2021-05-11

Signature: _____

Name: Mr. Honghao Zhou

Position: General Manager