

EU Certificate

Production Quality Assurance REGULATION (EU) 2017/745 on Medical Devices Annex XI Part A

Registration No.: DZ 2111577-1

Manufacturer: Shaoxing Yibon Medical Co., Ltd.
No. 347 Yuewang Road, Paojiang Industrial Zone,
Shaoxing,
312000 Zhejiang
P.R. China

EUDAMED Single
Registration No.: CN-MF-000003378

Products: Products of class I, sterile:
M020106 - COTTON GAUZES IN PIECES
- Sterile Gauze Swabs
M020102 - COTTON GAUZES, FOLDED
- Sterile Gauze Balls
M020204 - NON-WOVEN GAUZES IN PIECES
- Sterile Non-woven Swabs
M020201 - NON-WOVEN FOLDED GAUZES
- Sterile Non-woven Balls
M040201 - ABSORBENT DRESSINGS WITH CELLULOSE
PAD AND NON-WOVEN WRAPS
- Sterile Non-woven Absorbent Pads
M020203 - NON-WOVEN GAUZE PADS
- Non-woven Absorbent Pads
M020105 - COTTON GAUZE PADS
- Gauze Absorbent Pads
M040204 - NON-ADHERENT ABSORBENT DRESSINGS

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.

If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 244552767-200

Effective date: 2024-07-23

Expiry date: 2029-07-22

Issue date: 2024-07-23


Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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- Non-Adherent Absorbent Pads
M040301 - EYE PADS, COTTON OR NON-WOVEN
MATERIALS
- Sterile gauze eye pads
- Sterile Non-woven eye pads
- Sterile self adhesive eye pads
M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT
PAD
- Sterile non-woven wound dressing with pads
- Sterile film wound dressing with pads
- Sterile film wound dressing with pads with frame
M040102 - FIXING DRESSINGS
- Sterile non-woven wound dressing without pads
- Sterile film wound dressing without pads
- Sterile film wound dressing without pads with frame
- Sterile fixation strips
- Sterile fixation dressing Type A
- Sterile fixation dressing Type B
- Sterile fixation dressing Type C
M040406 - POLYURETHANE DRESSINGS
- Sterile foam dressings
M030301 - ELASTIC FIXING BANDAGES

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- Conforming bandages
M030402 - ELASTIC SUPPORT BANDAGES
- Elastic crepe bandages
M030101 - HYDROPHILIC GAUZE BANDAGES
- Woven gauze bandages
T020199 - SURGICAL DRAPES - OTHER
- Sterile drapes
T030102 - COVER SHEATHS, INSTRUMENTS AND
EQUIPMENTS
- Sterile CVK covers
A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL
AND COLLECTION - OTHER
- Sponge applicators
- Cotton applicators
- Gauze tipped applicators
- Non-woven tipped applicators
V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND
KITS, SINGLE-USE
- Medical scissors
- Medical scissors with plastic handle
- Medical metal forceps
- Medical plastic forceps

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- Kocher forceps
- Sterile stylets
- H900802 - SINGLE-USE NEEDLE HOLDERS
- Needle Holders
- H020101 - MECHANICAL SKIN STAPLERS
- Sterile staple removals
- T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING
SURGICAL INSTRUMENT KITS)
- Sterile catheterization sets
- Sterile suture removal sets
- Medical bowl sets
- Disinfection sets
- Sterile wound dressing sets
- Sterile Dialysis Sets
- Sterile staple removal sets
- A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
- Drainage sets

The scope of certification is limited to the aspects relating to
establishing, securing and maintaining sterile conditions

Authorized representative(s): OBELIS s.a.
Bd. Général Wahis, 53, 1030 Brussels, Belgium

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-07-23

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