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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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Precisely Right.

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
	- 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
Report No.:	244552767-200
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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
	- 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
Report No.:	244552767-200
Effective date:	2024-07-23
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Issue date:	2024-07-23

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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
	- 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
Report No.:	244552767-200
Effective date:	2024-07-23
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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

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

Report No.:	244552767-200
Effective date:	2024-07-23
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