

EU Certificate

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



Registration No.: DZ 2067318-1

Manufacturer: **Hubei V-Medical Products Co., Ltd.**
No. 67 Xianhong Road West, Xinlirenkou, Zhanggou Town, Xiantao City, 433012
Hubei, P.R. China

EUDAMED Single
Registration No.: CN-MF-000011268

Products: Products of class IIa:
M020102 - COTTON GAUZES, FOLDED
M020103 - LAPAROTOMY COTTON GAUZES

Products of Class Is:
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
M020102 - COTTON GAUZES, FOLDED
M020104 - STARCHED COTTON GAUZES
M020199 - COTTON GAUZES – OTHER
M020201 - NON-WOVEN FOLDED GAUZES
M020202 - NON-WOVEN LAPAROTOMY GAUZES
M0299 - GAUZES - OTHER
M030101 - HYDROPHILIC GAUZE BANDAGES
M030301 - ELASTIC FIXING BANDAGES
M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
T020101 - INCISION DRAPES
T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
T020401 - STANDARD SURGICAL GOWNS
T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR

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.: 190136114 120

Effective date: 2022-06-07

Expiry date: 2027-03-29

Issue date: 2022-06-07



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
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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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T030101 - COVER CAPS, INSTRUMENTS AND EQUIPMENT
V0102 - STAPLE REMOVER KNIVES, SINGLE-USE
V0199 - CUTTING DEVICES, SINGLE-USE - OTHER
V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE-USE
W050102 - URINE COLLECTION DEVICES
W050190 - SAMPLES COLLECTION DEVICES - VARIOUS

Authorised representative(s): **RAFFIN MEDICAL**
746 route de Sarcey 69490 Saint Romain De Popey France

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2022-06-07

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