

EU DECLARATION OF CONFORMITY / *Déclaration de conformité UE*

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| Name and address of manufacturer / <i>Nom et adresse du fabricant :</i> | Hubei V-Medical Products Co., Ltd. No. 67 Xianhong Road West, Xinlirenkou, Zhanggou Town, Xiantao City, 433012 Hubei Province, P.R.China |
| SRN of manufacturer / <i>SRN du fabricant :</i> | CN-MF-000011268 |
| EU Authorized Representative / <i>Mandataire européen :</i> | RAFFIN MEDICAL 746 route de Sarcey - 69490 SAINT ROMAIN DE POPEY - FRANCE |
| SRN of the EU Representative / <i>SRN du mandataire européen :</i> | FR-AR-000004632 |
| Trademark / Marque : |  |

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device / En tant que fabricant du dispositif médical suivant, nous déclarons par la présente, sous notre seule responsabilité, que le dispositif médical suivant:

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| Name of the medical device / <i>Nom du dispositif médical :</i> | Sterile Gauze Swabs <i>Compresses de gaze stériles</i> |
| Variant configurations / <i>Configurations variants :</i> | See Appendix <i>Voir l'annexe</i> |
| EMDN code / Code EMDN : | M020102 |
| Intended purpose / <i>Indication :</i> | It is used to cover/clean wounds or abrasions and absorb their exudates, absorb body-surface exudates. It is only intended to be used as a mechanical barrier; and not contact mucous membrane or manage the micro-environment of injured skin. <i>Destiné à couvrir/nettoyer les plaies ou les écorchures et absorber leurs exsudats, absorber les exsudats de la surface du corps. Uniquement destiné à être utilisé comme barrière mécanique et n'est pas destiné à entrer en contact avec les muqueuses ou à gérer le microenvironnement de la peau lésée.</i> |
| Basic UDI-DI / UDI-DI de base : | 697023378stgauzeSwabs9G |
| Applied standards / <i>Normes applicables :</i> | ENISO13485:2016;ENISO15223-1:2021;ENISO20417:2021; EN ISO 14971:2019; EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2013; EN ISO 10993-11:2018; EN 62366-1:2015; EN ISO 14644-1:2015; ENISO14644-2:2015; ASTM D4169:2016; |
| Class / Classe : | Is - rule 4 indent 1 according to annex VIII of Regulation (EU) 2017/745 <i>Is - règle 4, tiret 1, conformément à l'annexe VIII du Règlement (UE) 2017/745</i> |
| Conformity assessment / <i>Évaluation de la conformité :</i> | Annex XI, part A |
| Notified Body / <i>Organisme notifié :</i> | TÜV Rheinland LGA Products GmbH Tillystraße 2 , 90431 Nürnberg, Germany |
| NB Identification number / <i>Numéro d'identification ON :</i> | CE 0197 |
| Certificate No. / <i>Numéro de certificat :</i> | DZ2067318-1 |

Is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The declaration is valid in connection with the "final inspection report" of the device / Est conforme au Règlement (UE) 2017/745 et à toute autre législation pertinente de l'Union qui prévoit la délivrance de cette déclaration UE de conformité. La déclaration est valable en relation avec le "rapport d'inspection finale" du dispositif.

Hubei, 2024.12.20

Place, date

For and on behalf of
 湖北唯美医疗用品有限公司
 HUBEI V-MEDICAL PRODUCTS CO., LTD.
 ZhangGuoTai, General manager
 Name and function *Zhang Guotai*

Authorized Signature(s)

Appendix / Annexe

| REFERENCE | Trade name | Désignation |
|------------------|--------------------------------------------------------------|---------------------------------------------------------------------------|
| 010806 | Pouch of 1 sterile gauze swab 17x65 cm 6 ply 17 threads | <i>Sachet 1 compresse de gaze stérile 17x65cm 6 plis 17 fils</i> |
| 010811 | Pouch of 5 sterile gauze swabs 7,5x7,5 cm 8 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 7,5x7,5 cm 8 plis 17 fils</i> |
| 010817 | Pouch of 5 sterile gauze swabs 7,5x7,5 cm 12 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 7,5x7,5 cm 12 plis 17 fils</i> |
| 010820 | Pouch of 5 sterile gauze swabs 10x8 cm 8 ply 13 threads | <i>Sachet de 5 compresses de gaze stérile 10x8cm 8 plis 13 fils</i> |
| 010841 | Pouch of 20 sterile gauze swabs 10x10 cm 12 ply 17 threads | <i>Sachet de 20 compresses de gaze stérile 10x10 cm 12 plis 17 fils</i> |
| 010842 | Pouch of 5 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 010843 | Pouch of 10 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 10 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 010845 | Pouch of 1 sterile gauze swab 10x20 cm 24 ply 17 threads | <i>Sachet de 1 compresse de gaze stérile 10x20 cm 24 plis 17 fils</i> |
| 010848 | Pouch of 5 sterile gauze swabs 5x5 cm 8 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 5x5 cm 8 plis 17 fils</i> |
| 010849 | Pouch of 2 sterile gauze swabs 20x25 cm 16 ply 13 threads | <i>Sachet de 2 compresses de gaze stérile 20x25 cm 16 plis 13 fils</i> |
| 010850 | Pouch of 5 sterile gauze swabs 20x25 cm 16 ply 13 threads | <i>Sachet de 5 compresses de gaze stérile 20x25 cm 16 plis 13 fils</i> |
| 010851 | Pouch of 5 sterile gauze swabs 10x10 cm 12 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 10x10 cm 12 plis 17 fils</i> |
| 010854 | Pouch of 2 sterile gauze swabs 17x17 cm 12 ply 17 threads | <i>Sachet de 2 compresses de gaze stérile 17x17 cm 12 plis 17 fils</i> |
| 010855 | Pouch of 5 sterile gauze swabs 17x65 cm 6 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 17x65 cm 6 plis 17 fils</i> |
| 010860 | Pouch of 2 sterile gauze swabs 5x5 cm 12 ply 17 threads | <i>Sachet de 2 compresses de gaze stérile 5x5 cm 12 plis 17 fils</i> |
| 010865 | Pouch of 5 sterile gauze swabs 10x20 cm 16 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 10x20 cm 16 plis 17 fils</i> |
| 010895-1 | Meche packing sterile | <i>Packing mèche stérile</i> |
| 010907 | Pouch of 5 sterile gauze swabs 7,5x7,5 cm 8 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 7,5x7,5 cm 8 plis 17 fils</i> |
| 010908 | Pouch of 10 sterile gauze swabs 7,5x7,5 cm 12 ply 17 threads | <i>Sachet de 10 compresses de gaze stérile 7,5x7,5 cm 12 plis 17 fils</i> |
| 010910 | Pouch of 10 sterile gauze swabs 15x15 cm 16 ply 17 threads | <i>Sachet de 10 compresses de gaze stérile 15x15 cm 16 plis 17 fils</i> |
| 010935 | Pouch of 10 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 10 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 010938 | Pouch of 10 sterile gauze swabs 10x10 cm 12 ply 17 threads | <i>Sachet de 10 compresses de gaze stérile 10x10 cm 12 plis 17 fils</i> |
| 010941 | Pouch of 20 sterile gauze swabs 10x10 cm 12 ply 17 threads | <i>Sachet de 20 compresses de gaze stérile 10x10 cm 12 plis 17 fils</i> |
| 010952 | Pouch of 5 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 010953 | Pouch of 5 sterile gauze swabs 15x15 cm 16 ply 17 threads | <i>Sachet de 5 compresses de gaze stérile 15x15 cm 16 plis 17 fils</i> |
| 011007 | Pouch of 1 sterile gauze swabs 5x5 cm 12 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 5x5 cm 12 plis 17 fils</i> |
| 011008 | Pouch of 1 sterile gauze swabs 7,5x7,5 cm 12 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 7,5x7,5 cm 12 plis 17 fils</i> |
| 011009 | Pouch of 1 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |

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| 011010 | Pouch of 1 sterile gauze swabs 5x5 cm 12 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 5x5 cm 12 plis 17 fils</i> |
| 011011 | Pouch of 1 sterile gauze swabs 7,5x7,5 cm 12 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 7,5x7,5 cm 12 plis 17 fils</i> |
| 011012 | Pouch of 1 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 011013 | Pouch of 1 sterile gauze swabs 5x5 cm 12 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 5x5 cm 12 plis 17 fils</i> |
| 011027 | Pouch of 1 sterile gauze swabs 10x10 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 10x10 cm 16 plis 17 fils</i> |
| 011034 | Pouch of 2 sterile gauze swabs 7,5x7,5 cm 8 ply 17 threads | <i>Sachet de 2 compresses de gaze stérile 7,5x7,5 cm 8 plis 17 fils</i> |
| 011037 | Pouch of 2 sterile gauze swabs 10x10 cm 8 ply 17 threads | <i>Sachet de 2 compresses de gaze stérile 10x10cm 8 plis 17 fils</i> |
| 011088 | Pouch of 1 sterile gauze swabs 20x20 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 20x20 cm 16 plis 17 fils</i> |
| 011089 | Pouch of 1 sterile gauze swabs 30x30 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 30x30 cm 16 plis 17 fils</i> |
| 011090 | Pouch of 1 sterile gauze swabs 40x40 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 40x40 cm 16 plis 17 fils</i> |
| 011091 | Pouch of 1 sterile gauze swabs 40x40 cm 16 ply 17 threads | <i>Sachet de 1 compresses de gaze stérile 40x40 cm 16 plis 17 fils</i> |
| 300104 | Pouch of 10 sterile gauze swabs woven edges 30x30 cm 4 ply 17 threads | <i>Sachet de 10 compresses de gaze bords tissés stérile 30x30 cm 4 ply 17 threads</i> |
| 300201 | Pouch of 5 sterile gauze swabs woven edges 40x40 cm 4 ply 17 threads | <i>Sachet de 5 compresses de gaze bords tissés stérile 40x40 cm 4 plis 17 fils</i> |
| 300203 | Pouch of 1 sterile gauze swabs woven edges 60x60 cm 4 ply 17 threads | <i>Sachet de 1 compresses de gaze bords tissés stérile 60x60 cm 4 plis 17 fils</i> |
| 300205 | Pouch of 2 sterile gauze swabs woven edges 30x30 cm 4 ply 17 threads | <i>Sachet de 2 compresses de gaze bords tissés stérile 30x30 cm 4 plis 17 fils</i> |
| 310115 | Pouch of 2 sterile gauze swabs woven edges 40x80 cm 4 ply 17 threads | <i>Sachet de 2 compresses de gaze bords tissés stérile 40x80 cm 4 plis 17 fils</i> |

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
Tillystraße 2 · 90431 Nürnberg · Germany

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

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

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 |
| | | |
| | | |

Report No.: 190136114 120

Effective date: 2022-06-07

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