

2022-03-01

To Whom It May Concern

This is to confirm that a Certification Audit for MDR was carried out on behalf of TÜV Rheinland LGA Products GmbH Notified Body (CE0197) as follows:

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

Scope: 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
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 DRAPE
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
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
W050190 - SAMPLES COLLECTION DEVICES – VARIOUS

Standards: MDR 2017/745 Annex XI

Date: 2021-12-27~30 (audit date)

Report No.: 190136114-120

The corrective action proposed by the company are acceptable, therefore the auditors have recommended that TÜV Rheinland LGA Products GmbH Notified Body (0197) Certificate for a Quality Assurance System should be issued.



Yuhong CHEN
Vice General Manager Medical Greater China
TÜV Rheinland (China) Ltd.