

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Hubei V-Medical Products Co., Ltd.
Xinlirenkou,
Xiantao
433012 Hubei
P.R. China

has established and applies a quality management system for medical devices
for the following scope:

(See attachment for Scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-14
Certificate Registration No.: SX 60146805 0001
An audit was performed. Report No.: 16806587 005
This Certificate is valid until: 2023-01-27

Certification Body



Date 2020-04-14



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60146805 0001
Report No.: 16806587 005

Organization: Hubei V-Medical Products Co., Ltd.
Xinlirenkou,
Xiantao
433012 Hubei
P.R. China

Scope:

Manufacture and Distribution of Sterile X-ray Detectable Gauze Swabs, Sterile X-ray Detectable Gauze Balls, Sterile X-ray Detectable Laparotomy Sponges, Gauze Swabs, Gauze Balls, Non-Woven Swabs, Bandages, Stockinettes, Absorbent Pads, Isolation Gowns, Surgical Drapes, Non-woven Balls, Suture Kits, Gauze Rolls, Eye Pads, Dressing Kits, Application Kits, Anaesthesia Kits, Urinary Probing Kits, Delivery Kits and Infusion Kits, Sterile Surgical kits for Intrauterine Contraception Operation;

Provision of Ethylene Oxide Sterilization Service for Single-use Medical Devices in accordance with EN ISO 11135:2014

Certification Body



Date: 2020-04-14



Business Stream Products
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Hubei V-Medical Products Co., Ltd.
Xinlirenkou,
Xiantao
433012 HUBEI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 14, 2020

Application for : QMS
Certificate No. : SX 60146805 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60146805 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Wenxiang Zhang

A handwritten signature in blue ink, appearing to read 'Zhang' or similar, written over the printed name.

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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