



Product Service

Certificate

No. Q6 079078 0013 Rev. 01

Holder of Certificate: Hangzhou Formed
Medical Devices Co., Ltd.

Building 3, No. 292 Gonghe North Road, Xindeng Town
Fuyang District
311404 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Production and Distribution of Laryngeal Mask,
Tracheal Tube Introducer, Catheter Mount,
Hemorrhoidal Device, Endotracheal Tube,
Naso-Pharyngeal Airway, Oral-Pharyngeal Airway,
Feeding Tube, Oxygen Mask with Reservoir Bag,
Nasal Cannula, Oxygen Mask, Nebulizer kit,
Silicone Mask, Nasogastric Tube,
Suction Tubing with Yankauer Handle,
Intubating Stylet, Venturi Mask, Anaesthetic Mask,
Gastric Calibration Tube, Nelaton Catheter, Hydrophilic
Urinary Catheter, Catheterization Kit, Suction Catheter,
Urine Bag, Foley Catheter, Breathing System Filter,
Disposable Breathing Circuit, Suction Reservoir,
Drainage Tube, Wound Drainage System, Stomach
Tube, Heat and Moisture Exchanger, Drainage Bag,
Hydrophilic Urinary Catheter Kit, Ileostomy Catheter

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19104104

Valid from: 2019-09-23

Valid until: 2022-08-04

Date, 2019-09-23

Stefan Preiß

Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Hangzhou Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town, Fuyang
District, 311404 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT