ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 077591 0020 Rev. 00

M.S.D.N: 0401823561 - C.T.T.N.H.H
CÔNG TY TNHH MTV THIẾT BỊ Y TẾ THANH LỘC PHÁT
THÀNH PHỐ ĐÀ NẴNG

GIÁM ĐỐC
Phạm Công Toàn

Manufacturer	**Hitec Medical Co., Ltd.** No. 703, Hengnan RD 1328 Minhang District 201114 Shanghai PEOPLE'S REPUBLIC OF CHINA
Product Category(ies):	**Oropharyngeal Airway, Disposable Rectal Tube, Nasopharyngeal Airway, Urine Bag, Spigot**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2S 077591 0020 Rev. 00

Report No.: SH21709EXT01

Valid from: 2021-05-12
Valid until: 2024-05-26
Date, 2021-05-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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