ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 01 68903 021

Manufacturer:
Smartdata Suzhou Co., LTD
F4, Building 7, 198 Jinshan Road
215011 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Disposable Podiatry Set,
Needle Holder/Clamp, Speculum,
Marker/Caliper, Lasek Alcohol Well,
Retractor, Lasik Cannula (Single Hole at Tip),
IV Bag Safety Connector,
Trimano Application-Dressing Tray Pack,
Disposable Biopsy Valve,
Disposable Endoscope Bite Block and
Disposable Endoscope Valves Set
(Air/Water Valve, Suction Valve and Biopsy Valve)

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. See also notes overleaf.

Report No.: SH1740713

Valid from: 2017-03-31
Valid until: 2019-03-24

Date, 2017-03-31

Stefan Preiß

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

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Facility(ies):

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F4, Building 7, 198 Jinshan Road, 215011 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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