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

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 68903 024

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):

Forceps, Scissors, Hook/Chopper,
Punch, Fixation Ring, Peeler, Curette,
Dilator, Depressor,
Ophthalmic Surgical Customized Pack,
Irrigation Aspiration Cannula,
Vitreo-Retinal Instrument,
Disposable Suction Cannulas,
Single Use Elastic Stay Retractor,
Single Use Suction Tubes

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH1740715

Valid from: 2018-03-06
Valid until: 2019-07-08

Date, 2018-03-06

Stefan Preiß

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

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Facility(ies):

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

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