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

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Date: 2021.08.08 18:07:46 EEST
Reason: MoldSign Signature
Location: Moldova

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 03 65913 015

Manufacturer:

Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
No.51, Shuishan Road
Zhonglou Economic Development District
213023 Changzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56
40239 Duesseldorf
GERMANY

Digitally signed by Rotari Vladimir
Date: 2021.06.27 11:39:12 EEST
Reason: MoldSign Signature
Location: Moldova

Product Category(ies):

Linear Staplers Series Products, Circular Staplers Series Products, Disposable Trocar Series Products, Endobronchial Blocker Tube Series Products

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1823511

Valid from: 2018-05-11
Valid until: 2023-03-30

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Date, 2018-05-11

Stefan Preiß

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