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

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 04 93930 005

Manufacturer:

Berpu Medical Technology Co., Ltd
No.14 Xingji Road
Yongxing Street, Longwan District
325000 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Sterile "Infusion Sets, Intravenous Needles, Hypodermic Needles, Auto-disable Syringes, Insulin Syringes, Medical Stainless Steel Tube, Disposable Syringes, Burette Set, Dental Needles, Insulin Needles, Blood Collecting Needles, Self-destruction Safety Syringes, Transfusion Sets" for Single Use,
Sterile safety hypodermic needles for single use, safety insulin needle for single use.

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.: BJ1884407

Valid from: 2018-05-28
Valid until: 2023-05-27

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Date, 2018-05-14

Stefan Preiß

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

Digitally signed by Chirtoacă Iurie
Date: 2022.05.20 16:44:42 EEST
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Facility(ies):

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