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 IIa, IIb or III)

No. G2 045876 0015 Rev. 02

Manufacturer:
Changzhou Huichun Medical Equipment Co., Ltd.
Sanhekou, Zhenglu Town
213115 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

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

Product Category(ies):
Sterile Hypodermic Syringe for Single Use,
Sterile Hypodermic Syringe Needle for Single Use,
Infusion Set for Single Use,
Blood Collection Needle for Single Use,
Disposable Biopsy Forceps,
Sterile Insulin Syringe for Single Use,
Transfusion Sets for Single Use,
Intravenous Needles for Single Use

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.: SH19160EXT01

Valid from: 2019-08-24
Valid until: 2024-05-27

Date, 2019-05-24

Digitally signed by Guțan Ghenadie
Date: 2019.10.17 09:37:39 EEST
Reason: MoldSign Signature
Location: Moldova

Stefan Preiß

Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany