Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 076229 0004 Rev. 02

Manufacturer:

Weihai Weigao Blood Purification Products Co., Ltd.
No.20 Xingshan Road
Weihai Torch Hi-tech Science Park
264210 Weihai, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Weihai Weigao Blood Purification Products Co., Ltd.
No.20 Xingshan Road, Weihai Torch Hi-tech Science Park,
264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Extracorporeal Blood Circuit for Blood Purification Equipment, Hollow Fiber Dialyzer, A.V.Fistula Needle Sets, Hollow Fiber Hemodiafiltration.**

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.: BJ19773071

Valid from: 2019-08-13
Valid until: 2024-05-26

Date, 2019-08-13

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Şarco Alexandru
Date: 2021.04.18 09:46:24 EEST
Reason: MoldSign Signature
Location: Moldova

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

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