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 089357 0004 Rev. 00

Manufacturer: **Suzhou Jun Kang Medical Technology Co., Ltd.**
No. 28, Wutaishan RD, SND (SSTT)
215163 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Hollow Fiber Hemodialyzer and High Flux Hemodialyzer**

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.: SH19909EXT01

Valid from: 2019-10-18
Valid until: 2024-05-26

Digitally signed by Guțan Ghenadie
Date: 2022.02.16 17:00:44 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2019-10-18

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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No. G1 089357 0004 Rev. 00

Facility(ies):

Suzhou Jun Kang Medical Technology Co., Ltd.
No. 28, Wutaishan RD, SND (SSTT), 215163 Suzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

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

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