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 I in sterile conditions, sterilized systems or procedure packs)

No. G1S 099669 0004 Rev. 00

Manufacturer:

Meinntech Co., Ltd.
301, 401, 501, 502, A-dong
387, Simin-daero, Dongan-gu
Anyang-si, Gyeonggi-do 14057
REPUBLIC OF KOREA

Product Category(ies):

Sterile single-use IV Regulator sets for administration of the fluid from a container into a patient's vascular system

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 74952121

Valid from: 2020-05-19
Valid until: 2023-07-18

Date, 2020-05-19

Christoph Dicks
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