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

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 099669 0003 Rev. 00

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

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Sales of Cylinder Pump, Cylinder cartridge and Sterile IV Regulator sets**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74952121

Valid from: 2020-05-19
Valid until: 2021-07-18

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

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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 099669 0005 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): Cylinder Cartridge Set and Cylinder Pump

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.: 74952121

Valid from: 2020-05-19
Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

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

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