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www.zlg.de
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TÜV SÜD 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 086700 0009 Rev. 00

Manufacturer:

Supplymed Co., Ltd.
18/44 Moo.5 Tumbol Nadee,
Amphur Muang Samutsakhon
Samutsakhon 74000
THAILAND

EC-Representative:

Obelis s.a
53, Boulevard General Wahis,
1030 Brussels, BELGIUM

Product Category(ies): Haemodialysis Concentrates

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.: TH0161018T101

Valid from: 2018-12-18
Valid until: 2023-12-17

Date, 2018-12-18

Stefan Preiß

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

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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 086700 0009 Rev. 00

Facility(ies):

Supplymed Co., Ltd.
399/20 Moo.8 Tumbol Suanluang,
Amphur Krathumbaen,
Samutsakhon 74110, THAILAND

Supplymed Co., Ltd.
18/44 Moo.5 Tumbol Nadee,
Amphur Muang Samutsakhon,
Samutsakhon 74000, THAILAND

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