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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 064517 0010 Rev. 01

Manufacturer: **ADVITOS GmbH**
Agnes-Pockels-Bogen 1
80992 München
GERMANY

Facility(ies): ADVITOS GmbH
Agnes-Pockels-Bogen 1, 80992 München, GERMANY

Product Category(ies): hemodialysis device

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.: 713166289

Valid from: 2019-09-03
Valid until: 2023-06-30

Date, 2019-09-03

Stefan Preiß
Head of Certification/Notified Body

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

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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 064517 0009 Rev. 01

Manufacturer:

ADVITOS GmbH
Agnes-Pockels-Bogen 1
80992 München
GERMANY

Facility(ies):

ADVITOS GmbH
Agnes-Pockels-Bogen 1, 80992 München, GERMANY

Product Category(ies): Concentrates for Hemodialysis

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.

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