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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 037875 0044 Rev. 00

Manufacturer:

**KD Medical GmbH
Hospital Products**

Charlottenstrasse 65
10117 Berlin
GERMANY

Facility(ies):

KD Medical GmbH Hospital Products
Charlottenstrasse 65, 10117 Berlin, GERMANY

KD Medical (zhuhai) Co., Ltd.
No.288 East JiChang Road, JinWan, SanZao, 519040 Zhuhai,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infusion Sets, Transfusion Sets, Scalp Vein Sets,
Syringes, Syringes Insulin, Needles hypodermic,
Needles spinal, Needles dental, IV Cannulae
with and without safety feature, safety needles
(hypodermic needles with needle protection device),
Stopcocks, Extension Tubing, Fistula Needles,
Blood Lines for Haemodialysis, Oxygen Masks,
Blood lancets, Obturators, Pen needles, Blood Bags,
Syringes Infusion Pumps, Infusion Sets with
Burette, Needles epidural, Manifolds, Syringes
with re-use prevention feature with needle
(RUP syringes with needle)

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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Valid from: 2019-07-10

Valid until: 2024-05-26

Date, 2019-07-10

Stefan Preiß
Head of Certification/Notified Body