Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

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 015692 0502 Rev. 01

Manufacturer:

P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53
50996 Köln
GERMANY

Product Category(ies): **Sterile and non-sterile medical devices including medical disposables for anaesthesia, surgery, intensive care and ward equipment (class IIa and IIb) as well as spinal needles (class III)**

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.: 713163695+713175772

Valid from: 2020-07-13
Valid until: 2024-05-26

Date, 2020-07-13

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

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Medical Devices class IIa

Products / Product Groups:

Sterile autological blood transfusion systems
Filters
Sterile transfusion devices
Silicone respiratory tubes

Sterile scalpels and scalpel blades
Sterile redon bottles
Sterile suction tubes
Sterile suction kits
Sterile wound drainage systems
Sterile arterial embolectomy catheters

Humidifiers
Artificial noses

Sterile catheters and accessories
Sterile trocar and thoracic catheters

Oxygen therapy accessories
Accessories for respiration
Identy loops

Sterile Dermal Biospsy Punch

Faecal Management System

Medical Devices class IIb

Products / Product Groups:

Disposable electrosurgical pencils
Disposable neutral electrodes

Balloon catheter
Defibrillation electrodes

Medical Devices class III

Spinal needles

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