



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 015692 0504 Rev. 01

Manufacturer

P. J. Dahlhausen & Co. GmbH

Emil-Hoffmann-Str. 53
50996 Köln
GERMANY

Product Category(ies):

**Sterile medical disposables (class I) for
anaesthesia, surgery, intensive care and
ward equipment**

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 V. 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.:

713176899

Valid from:

2020-04-21

Valid until:

2024-05-26

Date,

2020-04-21

Christoph Dicks

Head of Certification/Notified Body



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Medical Devices Class I

Products/Product Groups:

Sterile Guedel airways
Sterile video camera drapes
Sterile examination gloves
Sterile catheter kits
Sterile suture removal kits
Sterile urine drainage bags
Sterile infusion accessories
Sterile Remover for skin stapler
Sterile cover for surgical light handle
Sterile umbilical cord clamp
Sterile scissors for external use
Sterile suction connecting tube
Sterile reservoir
Sterile stitch cutter for external use
Sterile thorax drainage system
Sterile tip cleaner
Sterile irrigation system
Sterile bag for irrigation system
Sterile thoracic drainage secretion bag
Sterile protection cover for ultrasound sensors