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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