



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

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

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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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  
 Identity loops

Sterile Dermal Biopsy 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