



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



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**

## 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

Page 2 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®