



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 13 04 15692 037

Manufacturer:

P. J. Dahlhausen & Co. GmbH

Emil-Hoffmann-Str. 53
50996 Köln
GERMANY

Facility(ies):

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)
for further details see attachment**

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.:

713023089/-1

Valid from:

2013-06-25

Valid until:

2018-05-19



Hans-Heiner Junker

Date, 2013-06-25

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

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Product Service

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

Medical Devices Class IIb

Products / Product Groups:

Disposable electrosurgical pencils
Disposable neutral electrodes

Balloon catheter
Defibrillation electrodes

Medical Devices Class III

Spinal needles

Munich, CRT2, 2013-06-25

Hans-Heiner Junker

