



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 18 02 15692 044

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.: 713125906_1

Valid from: 2018-05-20
Valid until: 2023-05-19



Date, 2018-05-18

Stefan Preiß

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

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Product Service

Attachment for Certificate no G1 18 02 15692 044
dated 2018-05-18

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, CRT, 2018-05-18

S. Preis

Stefan Preis



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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 18 02 15692 045

Manufacturer: P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53
50996 Köln
GERMANY



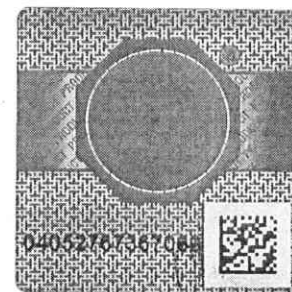
Facility(ies): P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53, 50996 Köln, GERMANY

Product Category(ies): Sterile medical disposables (class I) for anaesthesia, surgery, intensive care and ward equipment
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 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.

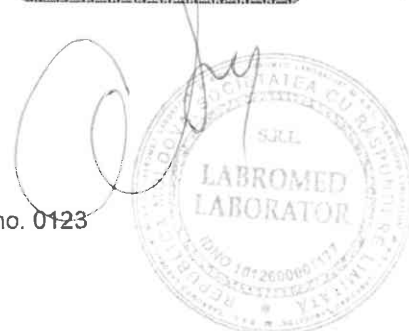
Report No.: 713125906_2

Valid from: 2018-06-07
Valid until: 2023-05-19



Date, 2018-06-07

S. Preis
Stefan Preis



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

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Product Service

Attachment to Certificate no G2S 18 02 15692 045
dated 2018-06-07

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

Munich, CRT, 2018-06-07

S. Preis

Stefan Preis



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LABORATORY



Product Service

Attachment to Certificate no G2S 18 02 15692 045
dated 2018-06-07

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

Munich, CRT, 2018-06-07

Stefan Preiß





Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 18 03 15692 048

Manufacturer: P. J. Dahlhausen & Co. GmbH

Emil-Hoffmann-Str. 53
50996 Köln
GERMANY



Product: Non-Active Medical Devices

Model(s): Spinal Needle K-3 Lancet Point
Spinal Needle Pencil Point

Parameters: see attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

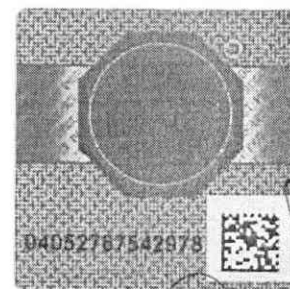
Report no.: 713124836

Valid from: 2018-04-24

Valid until: 2023-04-23

Date, 2018-04-19

Stefan Preiß



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

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Product Service

Attachment for Certificate no G7 18 03 15692 048
valid from 2018-04-24

Parameters:
Spinal Needle K-3 Lancet point

REF	Size	Length	Colour Code
76.111.18.030	18 G (1,25 mm)	3,0 inch (76 mm)	rose
76.111.18.035	18 G (1,25 mm)	3,5 inch (89 mm)	rose
76.111.19.030	19 G (1,05 mm)	3,0 inch (76 mm)	ivory
76.111.19.035	19 G (1,05 mm)	3,5 inch (89 mm)	ivory
76.111.20.016	20 G (0,90 mm)	1,5 inch (38 mm)	yellow
76.111.20.030	20 G (0,90 mm)	3,0 inch (76 mm)	yellow
76.111.20.035	20 G (0,90 mm)	3,5 inch (89 mm)	yellow
76.111.21.030	21 G (0,80 mm)	3,0 inch (76 mm)	green
76.111.21.035	21 G (0,80 mm)	3,5 inch (89 mm)	green
76.111.22.015	22 G (0,72 mm)	1,5 inch (38 mm)	black
76.111.22.030	22 G (0,72 mm)	3,0 inch (76 mm)	black
76.111.22.035	22 G (0,72 mm)	3,5 inch (89 mm)	black
76.111.22.120	22 G (0,72 mm)	4,72 inch (120 mm)	black
76.111.23.035	23 G (0,63 mm)	3,5 inch (89 mm)	light blue
76.111.25.030	25 G (0,53 mm)	3,0 inch (76 mm)	orange
76.111.25.035	25 G (0,53 mm)	3,5 inch (89 mm)	orange
76.111.25.036	25 G (0,53 mm) with introducer needle 20 G (0,90 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	orange
76.111.25.120	25 G (0,53 mm) with introducer needle 20 G (0,90 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	orange
76.111.26.020	26 G (0,47 mm) with introducer needle 20 G (0,90 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	brown
76.111.27.035	27 G (0,42 mm) with introducer needle 22 G (0,72 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	grey
76.111.27.120	27 G (0,42 mm) with introducer needle 22 G (0,72 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	grey





Attachment for Certificate no G7 18 03 15692 048
valid from 2018-04-24

Parameters:

Spinal Needle Pencil Point

REF	Size	Length	Colour Code
76.222.22.035	22 G (0,72 mm)	3,5 inch (89 mm)	black
76.222.22.036	22 G (0,72 mm) with introducer needle 18 G (1,25 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	black
76.222.22.120	22 G (0,72 mm)	4,72 inch (120 mm)	black
76.222.22.150	22 G (0,72 mm) with introducer needle 18 G (1,25 mm)	5,9 inch (150 mm) 1,5 inch (38 mm)	black
76.222.24.035	24 G (0,55 mm) with introducer needle 20 G (0,90 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	violet
76.222.24.120	24 G (0,55 mm) with introducer needle 20 G (0,90 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	violet
76.222.25.035	25 G (0,59 mm) with introducer needle 20 G (0,90 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	orange
76.222.25.120	25 G (0,59 mm) with introducer needle 20 G (0,90 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	orange
76.222.26.035	26 G (0,47 mm) with introducer needle 20 G (0,90 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	brown
76.222.26.120	26 G (0,59 mm) with introducer needle 20 G (0,90 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	brown
76.222.27.035	27 G (0,42 mm) with guide needle 22 G (0,72 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	grey
76.222.27.120	27 G (0,42 mm) with introducer needle 22 G (0,72 mm)	4,72 inch (120 mm) 1,5 inch (38 mm)	grey
76.222.29.035	29 G (0,35 mm) with introducer needle 22 G (0,72 mm)	3,5 inch (89 mm) 1,5 inch (38 mm)	red

Munich, MHS-CRT, 2018-04-19

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Product Service

CERTIFICATE

No. Q5 18 03 15692 049

Holder of Certificate: 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



Certification Mark:



Scope of Certificate: Design and development, Configuration and Distribution of medical products for anaesthesia, surgery intensiv care and ward

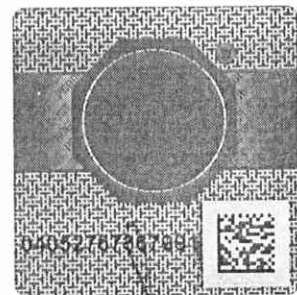
Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713128266

Valid from: 2018-07-01
Valid until: 2021-06-30



Date, 2018-06-22

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00