



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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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



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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

Stefan Preiß