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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 012974 0592 Rev. 02

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product:

Spinal Needles

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.:

713164389

Valid from:

2020-05-13

Valid until:

2024-05-26

Date,

2020-05-13

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

Pencan® / Spinocan® / Atraucan®

Parameter:

Atraucan® Needles:

OHD / Current Hub Design	Product Name	O.D. x length / Gauge x length
4504739	Atraucan®	0.47 x 88 mm / 26G x 3½"
4504763	Atraucan® Paed	0.47 x 50 mm / 26G x 2"
4504771	Atraucan® Paed	0.47 x 25 mm / 26G x 1"

Pencan® Needles:

OHD / Current Hub Design	Product Name	O.D. x length / Gauge x length
4502035	Pencan®	0.73 x 88 mm / 22G x 3½"
4502019	Pencan®	0.53 x 88 mm / 25G x 3½"
4502043	Pencan®	0.53 x 88 mm / 25G x 3½"
4502116	Pencan®	0.53 x 103 mm / 25G x 4"
333877	Pencan®	0.53 x 156 mm / 25G x 6¼"
4502027	Pencan®	0.42 x 88 mm / 27G x 3½"
4502051	Pencan®	0.42 x 88 mm / 27G x 3½"
4502124	Pencan®	0.42 x 103 mm / 27G x 4"
4502132	Pencan®	0.42 x 120 mm / 27G x 4¾"
4502175	Pencan® Paed	0.42 x 50 mm / 27G x 2"
4502167	Pencan® Paed	0.53 x 25 mm / 25G x 1"
4502159	Pencan® Paed	0.53 x 50 mm / 25G x 2"

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NHD / New Hub Design		
4502019-01	Pencan®	0.5 x 88 mm / 25G x 3½"
4502027-01	Pencan®	0.4 x 88 mm / 27G x 3½"
4502035-13	Pencan®	0.7 x 88 mm / 22G x 3½"
4502043-13	Pencan®	0.5 x 88 mm / 25G x 3½"
4502051-13	Pencan®	0.4 x 88 mm / 27G x 3½"
4502116-13	Pencan®	0.5 x 103 mm / 25G x 4"
4502124-13	Pencan®	0.4 x 103 mm / 27G x 4"
4502132-13	Pencan®	0.4 x 120 mm / 27G x 4¾"
4502120-13	Pencan®	0.5 x 120 mm / 25G x 4¾"
4502159-13	Pencan®	0.5 x 50 mm / 25G x 2"
4502167-13	Pencan®	0.5 x 25 mm / 25G x 1"
4502175-13	Pencan®	0.4 X 50 mm / 27G x 2"
4502019-10	Pencan®	0.5 X 88 mm / 25G x 3½"
4502027-10	Pencan®	0.4 X 88 mm / 27G x 3½"



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NRFit®		
4502019N-01	Pencan® NRFit®	0.5 x 88mm / 25G x 3½"
4502027N-01	Pencan® NRFit®	0.4 x 88mm / 27G x 3½"
4502035N-01	Pencan® NRFit®	0.7 x 88mm / 22G x 3½"
4502043N-01	Pencan® NRFit®	0.5 x 88mm / 25G x 3½"
4502044N-01	Pencan® NRFit®	0.5 x 88mm / 25G x 3½"
4502051N-01	Pencan® NRFit®	0.4 x 88mm / 27G x 3½"
4502052N-01	Pencan® NRFit®	0.4 x 88mm / 27G x 3½"
4502116N-01	Pencan® NRFit®	0.5 x 103mm / 25G x 4"
4502117N-01	Pencan® NRFit®	0.5 x 103mm / 25G x 4"
4502124N-01	Pencan® NRFit®	0.4 x 103mm / 27G x 4"
4502125N-01	Pencan® NRFit®	0.4 x 103mm / 27G x 4"
4502132N-01	Pencan® NRFit®	0.4 x 120mm / 27G x 4¾"
4502120N-01	Pencan® NRFit®	0.5 x 120mm / 25G x 4¾"
4502159N-01	Pencan® NRFit®	0.5 x 50mm / 25G x 2"
4502167N-01	Pencan® NRFit®	0.5 x 25mm / 25G x 1"
4502175N-01	Pencan® NRFit®	0.4 X 50mm / 27G x 2"
333877N-01	Pencan® NRFit®	0.5 x 156mm / 25G x 6.1"



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Spinocan® Needles:

OHD / Current Hub Design	Product Name	O.D. x length / Gauge x length
4501373	Spinocan®	1.3 x 75 mm / 18G x 3"
4501390	Spinocan®	1.3 x 88 mm / 18G x 3½"
4501144	Spinocan®	1.1 x 40 mm / 19G x 1½"
4501195	Spinocan®	1.1 x 88 mm / 19G x 3½"
4509757	Spinocan®	0.9 x 75 mm / 20G x 3"
4509900	Spinocan®	0.9 x 88 mm / 20G x 3½"
4507401	Spinocan®	0.7 x 40 mm / 22G x 1½"
4507754	Spinocan®	0.7 x 75 mm / 22G x 3"
4507908	Spinocan®	0.7 x 88 mm / 22G x 3½"
4506090	Spinocan®	0.7 x 120 mm / 22G x 4¾"
4505751	Spinocan®	0.53 x 75 mm / 25G x 3"
4505905	Spinocan®	0.53 x 88 mm / 25G x 3½"
4505913	Spinocan®	0.53 x 120 mm / 25G x 4¾"
4502906	Spinocan®	0.47 x 88 mm / 26G x 3½"
4504917	Spinocan®	0.47 x 120 mm / 26G x 4¾"
4502140	Spinocan®	0.42 x 120 mm / 27G x 4¾"
4503902	Spinocan®	0.42 x 88 mm / 27G x 3½"
4501900	Spinocan®	0.35 x 88 mm / 29G x 3½"
4501918	Spinocan®	0.35 x 120 mm / 29G x 4¾"

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NHD / New Hub Design		
4501144-13	Spinocan®	1.1 x 40 mm / 19G x 1½"
4501195-13	Spinocan®	1.1 x 88 mm / 19G x 3½"
4506014-03	Spinocan®	0.6 x 88 mm / 23G x 3½"
4501373-13	Spinocan®	1.3 x 75 mm / 18G x 3"
4501390-01	Spinocan®	1.3 x 88 mm / 18G x 3½"
4501900-13	Spinocan®	0.33 x 88 mm / 29G x 3½"
4501918-13	Spinocan®	0.33 x 120 mm / 29G x 4¾"
4502140-13	Spinocan®	0.4 x 120 mm / 27G x 4¾"
4502906-01	Spinocan®	0.45 x 88 mm / 26G x 3½"
4503902-01	Spinocan®	0.4 x 88 mm / 27G x 3½"
4504917-13	Spinocan®	0.45 x 120 mm / 26G x 4¾"
4505751-01	Spinocan®	0.5 x 75 mm / 25G x 3"
4505905-01	Spinocan®	0.5 x 88 mm / 25G x 3½"
4505913-13	Spinocan®	0.5 x 120 mm / 25G x 4¾"
4506090-13	Spinocan®	0.7 x 120 mm / 22G x 4¾"
4507401-13	Spinocan®	0.7 x 40 mm / 22G x 1½"
4507754-13	Spinocan®	0.7 x 75 mm / 22G x 3"
4507908-01	Spinocan®	0.7 x 88mm / 22G x 3½"
4509757-13	Spinocan®	0.9 x 75 mm / 20G x 3"



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4509900-01	Spinocan®	0.9 x 88 mm / 20G x 3½"
4501390-10	Spinocan®	1.3 x 88 mm / 18G x 3½"
4502906-10	Spinocan®	0.45 x 88 mm / 26G x 3½"
4503902-10	Spinocan®	0.45 x 88 mm / 27G x 3½"
4505751-10	Spinocan®	0.5 x 75 mm / 25G x 3"
4505905-10	Spinocan®	0.5 x 88 mm / 25G x 3½"
4507908-10	Spinocan®	0.7 x 88 mm / 22G x 3½"
4509900-10	Spinocan®	0.9 x 88 mm / 20G x 3½"
NRFit®		
4501900N-01	Spinocan® NRFit®	0.33 x 88mm / 29G x 3½"
4501901N-01	Spinocan® NRFit®	0.33 x 88mm / 29G x 3 ½"
4501144N-01	Spinocan® NRFit®	1.1 x 40mm / 19G x 1½"
4501195N-01	Spinocan® NRFit®	1.1 x 88mm / 19G x 3½"
4501373N-01	Spinocan® NRFit®	1.3 x 75mm / 18G x 3"
4501390N-01	Spinocan® NRFit®	1.3 x 88mm / 18G x 3½"
4501918N-01	Spinocan® NRFit®	0.33 x 120mm / 29G x 4¾"
4502140N-01	Spinocan® NRFit®	0.4 x 120mm / 27G x 4¾"
4502906N-01	Spinocan® NRFit®	0.45 x 88mm / 26G x 3½"
4503902N-01	Spinocan® NRFit®	0.4 x 88mm / 27G x 3½"
4504917N-01	Spinocan® NRFit®	0.45 x 120mm / 26G x 4¾"

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4505751N-01	Spinocan® NRFit®	0.5 x 75mm / 25G x 3"
4505905N-01	Spinocan® NRFit®	0.5 X 88mm / 25G x 3½"
4505913N-01	Spinocan® NRFit®	0.5 X 120mm / 25G x 4¾"
4506090N-01	Spinocan® NRFit®	0.7 x 120mm / 22G x 4¾"
4506095N-01	Spinocan® NRFit®	0.7 x 150mm / 22G x 6"
4507401N-01	Spinocan® NRFit®	0.7 x 40mm / 22G x 1½"
4507754N-01	Spinocan® NRFit®	0.7 x 75mm / 22G x 3"
4507908N-01	Spinocan® NRFit®	0.7 x 88mm / 22G x 3½"
4509757N-01	Spinocan® NRFit®	0.9 x 75mm / 20G x 3"
4509900N-01	Spinocan® NRFit®	0.9 x 88mm / 20G x 3½"