



Certificate

No. Q5 012974 0590 Rev. 02

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Distribution, Installation and Servicing of:

Non-active Medical Devices (Sterile and Non-Sterile) for:

- Injection, Infusion, Transfusion and Nutrition
(Hypodermic Needles, Pen Cannulas for Subcutaneous Injection of Fluid Drug Products, Lancets for Blood Sampling, Intravenous Administration Sets, Tube Connectors, Closing Cones, Vascular Access Devices (Sterile Disposables for Infusion, Transfusion and Vein Puncture), Sterile Disposable Infusion Sets for Volume Control, Measuring of Central Venous Pressure, Filters and Stopcocks for Infusion Therapy, Oral Dispenser (sterile and non-sterile), Withdrawal and Injection Spikes and Needles for Drug Admixture, Syringes, Administration Sets for Enteral Nutrition Therapy)

- Wound care
(Bandages and Retainers for Compression and Fixation, Sterile Products, Disposables and Sets for Wound Care)

- Anesthesia, Emergency, Intensive and Home Care
(Central Venous Catheter Sets for Catheterization of the Superior Vena Cava, Needles and Catheters and Sets for Spinal and Epidural Anesthesia, Needles and Catheters and Sets for Plexus Anesthesia, Needles and Catheters and Sets for Central and Peripheral Regional Anesthesia, Needles and Catheters and Sets for Combined Spinal and Epidural Anesthesia, Sets for Pleura- and Thorax Drainage, Thoracic Aspiration Set, Wound Drainage System, Sets for Fine Needle Biopsy and Percutaneous Liver Biopsy, Sets for Urology, Nephrology and Incontinence)

- Disinfecting, Cleaning and Rinsing

- Irrigation
(Administration Accessories, Fixation Accessories for Stoma and Rectal Irrigation)

- Cryotherapy

- Configured Customized Sets

Non-active Medical Devices (Sterile and Non-Sterile):

- Medical Gloves
(Examination and Surgical Gloves for Surgical and Aseptic Medical

Certificate

No. Q5 012974 0590 Rev. 02

Applications)

- Sterile Solutions

Active Medical Devices for:

- Fluid Management
(Infusion Pumps, including Management Units, and Software, and
Elastomeric Infusion Pumps)

- Nerve Stimulation
(Nerve Stimulators for Peripheral Regional Anesthesia)

- Wound Drainage System

- Enteral Feeding

- Irrigation
(Irrigation Pump with Power Supply for Stoma and Rectal Irrigation)

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 012974 0590 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_012974_0590_Rev.02)

Report No.: 713218550

Valid from: 2022-01-13

Valid until: 2024-10-21

Date, 2022-01-13



Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 012974 0590 Rev. 02

Applied Standard(s):

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

Facility(ies):

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Headquarters, of Division Hospital Care
 Management
 Quality Management

B. Braun Melsungen AG OPM
Carl-Braun-Straße 1, 34212 Melsungen, GERMANY

Headquarters, of Out Patient Market
 Management
 Quality Management

B. Braun Melsungen AG Werk A und K
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Design and Development, Manufacture of:
 Sterile Solutions

Manufacture of Non-active Medical Devices for:
 Anesthesia, Emergency, Intensive and Home Care
 Injection, Infusion, Transfusion and Nutrition

B. Braun Melsungen AG Werk B
Dörnbach 10, 34286 Spangenberg, GERMANY

Design and Development, Manufacture of:
 Configured Customized Sets

B. Braun Melsungen AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

Service of Active Medical Devices for:
 Fluid Management

B. Braun Melsungen AG Werk E
Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY

Design and Development, Manufacture of Active and Non-active
 Medical Devices for:

Injection, Infusion, Transfusion and Nutrition
 Anesthesia, Emergency, Intensive and Home Care
 Nerve Stimulation (Nerve Stimulators for Peripheral Regional
 Anesthesia)
 Wound Drainage System
 Enteral Feeding

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No. Q5 012974 0590 Rev. 02

B. Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY

Manufacture of Non-active Medical Devices for:
Injection, Infusion, Transfusion and Nutrition
Central Laboratories,
Central Warehouse, Supply Chain Management
Central Sterilization (Radiation)

B. Braun Melsungen AG
Am Buschberg 1, 34212 Melsungen, GERMANY

Headquarters, of Center of Excellence Automated Infusion
Systems

Management of Active Medical Devices for

Fluid Management
(Infusion Pumps, including Management Units, and Software)

Irrigation
(Irrigation Pump with Power Supply for Stoma and Rectal
Irrigation)

B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

Design and Development, Manufacture of:
Non-active Medical Devices for:
Emergency, Intensive and Home Care

B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

Design and development, Control of production, distribution,
installation and servicing
of products for the injection, infusion, transfusion, incontinence
care, stoma care, wound care, diabetes care, urology, disinfecting,
cleaning and rinsing, cryotherapy, irrigation (Administration
Accessories, Fixation Accessories for Stoma and Rectal Irrigation),
medical gloves for single use, protection clothing, medical waste
container, home care of patients.
Individual compounded parenteral nutrition.



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Product Service

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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 012974 0607 Rev. 02

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Active medical devices for fluid management:

- Volumetric infusion pumps
- Infusion syringe pumps
- Control & organisation units and systems made out o fit
- Irrigation Pump and accessories
- Enteral feeding pumps
- Devices for nerve stimulation
- Pump for negative pressure wound therapy

Non-active medical devices (sterile and non-sterile) for:

- Injection, infusion, transfusion and nutrition
 - Anaesthesia, emergency, intensive and home care
 - Disinfecting, cleaning, rinsing
 - Irrigation
 - Cryotherapy
 - Configured customized sets
 - Medica devices for wound care
 - Medical Gloves
 - Sterile solutions (Irrigation Solutions)
- Sterile products for urology and gastroenterology:
- Catheters, catheter kits, drainage and irrigation kits, urological stents, nephrostomy kits, cystometry kits, accessories

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.: 713181267

Valid from: 2020-06-09

Valid until: 2024-05-26

Date, 2020-06-09

Christoph Dicks
Head of Certification/Notified Body

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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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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

Model(s): Pengan® / 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"

Pengan® Needles:

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

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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

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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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

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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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

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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No. G7 012974 0592 Rev. 02

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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 (Devices in Class III)

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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"

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ANOTACIÓN EN EL REGISTRO DE COMUNICACIONES DE PRODUCTOS SANITARIOS

(Art. 22 del Real Decreto 1591/2009, de 16 de Octubre, por el que se regulan los productos sanitarios)

Con fecha 07 de junio de 2019 ha sido anotada en el Registro de Comunicaciones de Productos Sanitarios de la Agencia Española de Medicamentos y Productos Sanitarios (CCPS), la comunicación de comercialización y/o puesta en servicio del producto con denominación:

DENOMINACIÓN

Pencan / Pencan Paed

COMUNICADO POR

B. Braun Medical, S.A.

ESPAÑA

08191 Rubí

Carretera de Terrassa, 121

FABRICANTE

B. Braun Melsungen AG

ALEMANIA

34212 Melsungen

Carl-Braun-Str. 1

No procede añadir representante europeo autorizado

a la que le ha correspondido el número de identificación en el registro:

PS/2010/1456

Página adicional de modelos/variantes incluidos en esta comunicación.

Nota.- Esta notificación no tiene el carácter de una autorización sanitaria de comercialización, ni entraña un juicio sobre la conformidad del producto con la legislación vigente. Únicamente avala el cumplimiento del procedimiento de comunicaciones de comercialización y/o puesta en servicio de productos sanitarios.



DOCUMENTO DE MODELOS/VARIANTES

Subgenérico: *Agujas espinales*

Descripción: *Aguja espinal para punción espinal y de diagnóstico.*

Finalidad: *Anestesia intradural (inyección de anestésicos locales en el espacio subaracnoideo con fines diagnósticos, procedimientos quirúrgicos y tratamiento del dolor. Punción lumbar (diagnóstico)).*

Modelo(s) / Variante(s)	
Referencia	Nombre
333877-05	Pencan
333877N-01	Pencan NRFit
4502019	Pencan
4502019-01	Pencan
4502019-10	Pencan
4502019N-01	Pencan NRFit
4502027	Pencan
4502027-01	Pencan
4502027-10	Pencan
4502027N-01	Pencan NRFit
4502035	Pencan
4502035-13	Pencan
4502035S-13	Pencan SafeConnect
4502035N-01	Pencan NRFit
4502043	Pencan
4502043-13	Pencan
4502043N-01	Pencan NRFit
4502043S-13	Pencan SafeConnect
4502044N-01	Pencan NRFit
4502051	Pencan
4502051-13	Pencan
4502051N-01	Pencan NRFit
4502051S-13	Pencan SafeConnect



Modelo(s) / Variante(s)

Referencia	Nombre
4502052N-01	Pencan NRFit
4502116	Pencan
4502116-13	Pencan
4502116N-01	Pencan NRFit
4502116S-13	Pencan SafeConnect
4502117N-01	Pencan NRFit
4502120-13	Pencan
4502120N-01	Pencan NRFit
4502120S-13	Pencan SafeConnect
4502121S-13	Pencan SafeConnect
4502124	Pencan
4502124-13	Pencan
4502124N-01	Pencan NRFit
4502124S-13	Pencan SafeConnect
4502125N-01	Pencan NRFit
4502125S-13	Pencan SafeConnect
4502132	Pencan
4502132-13	Pencan
4502132N-01	Pencan NRFit
4502132S-13	Pencan SafeConnect
4502159	Pencan Paed
4502159-13	Pencan
4502159N-01	Pencan NRFit
4502159S-13	Pencan SafeConnect
4502167	Pencan Paed
4502167-13	Pencan
4502167N-01	Pencan NRFit
4502167S-13	Pencan SafeConnect
4502175	Pencan Paed



Modelo(s) / Variante(s)

Referencia	Nombre
4502175N-01	Pencan NRFit
4502175-13	Pencan
4502183	Pencan Paed
4502248	Pencan
4502256	Pencan

