



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 012974 0640 Rev. 00

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

SRN Manufacturer - DE-MF-000000201

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s)

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. 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:G70 012974 0640 Rev. 00

Report No.: 713237217

Valid from: 2023-12-22

Valid until: 2028-12-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-22



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Classification: Class III
Device Group: A010301 - SPINAL AND EPIDURAL ANAESTHESIA NEEDLES AND KITS
Basic UDI-DI: 40392390000008612T
Intended Purpose: Spinal needle for intrathecal injections and diagnostic lumbar puncture.
Device(s): Atraucan®, Pencan, Spinocan®

Medical Device Name (trading name)	Individual Article Number of the Device
Atraucan®	4542601
Atraucan®	4542602
Atraucan®	4542603
Pencan	4532201
Pencan	4532501
Pencan	4532502
Pencan	4532503
Pencan	4532504
Pencan	4532505
Pencan	4532506
Pencan	4532507
Pencan	4532508
Pencan	4532510
Pencan	4532701
Pencan	4532702
Pencan	4532703
Pencan	4532704
Pencan	4532705
Pencan	4532706
Pencan	4532707
Pencan	4532201N
Pencan	4532501N
Pencan	4532502N
Pencan	4532503IN



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Medical Device Name (trading name)	Individual Article Number of the Device
Pencan	4532503N
Pencan	4532504IN
Pencan	4532504N
Pencan	4532505N
Pencan	4532506N
Pencan	4532507N
Pencan	4532508N
Pencan	4532510N
Pencan	4532701N
Pencan	4532702IN
Pencan	4532702N
Pencan	4532703IN
Pencan	4532703N
Pencan	4532704N
Pencan	4532705N
Pencan	4532706N
Pencan	4532707N
Spinocan®	4521801
Spinocan®	4522001
Spinocan®	4522201
Spinocan®	4522202
Spinocan®	4522203
Spinocan®	4522204
Spinocan®	4522301
Spinocan®	4522501
Spinocan®	4522502
Spinocan®	4522503
Spinocan®	4522601
Spinocan®	4522701
Spinocan®	4522702
Spinocan®	4522703
Spinocan®	4522901
Spinocan®	4521801IN
Spinocan®	4521801N
Spinocan®	4522001IN



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Medical Device Name (trading name)	Individual Article Number of the Device
Spinocan®	4522001N
Spinocan®	4522201N
Spinocan®	4522202N
Spinocan®	4522203IN
Spinocan®	4522203N
Spinocan®	4522204N
Spinocan®	4522301IN
Spinocan®	4522301N
Spinocan®	4522501N
Spinocan®	4522502IN
Spinocan®	4522502N
Spinocan®	4522503IN
Spinocan®	4522503N
Spinocan®	4522601IN
Spinocan®	4522601N
Spinocan®	4522701IN
Spinocan®	4522701N
Spinocan®	4522702N
Spinocan®	4522703N
Spinocan®	4522901N

The validity of this certificate ./.
depends on conditions and/or
is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2023-12-22	713237217	Initial issuance