



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 025701 0098 Rev. 00

Manufacturer:

B. Braun Surgical, S.A.

Ctra. de Terrassa, 121
08191 Rubí (Barcelona)
SPAIN

SRN Manufacturer:

ES-MF-000002083

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 025701 0098 Rev. 00

Report No.:

713204468

Valid from:

2022-12-12

Valid until:

2027-12-11

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2022-12-12



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No. G70 025701 0098 Rev. 00

Classification: III
Device Group: H01010104 - SYNTHETIC RESORBABLE SUTURES WITH ANTIBACTERIAL MULTIFILAMENT
Basic UDI-DI: 40392390000005582P
Intended Purpose: The intended purpose of Novosyn® CHD is for soft tissue approximation and/or ligation. Novosyn CHD is coated with the antibacterial agent chlorhexidine diacetate to reduce the risk of bacterial attachment and colonization of the suture.
Device(s): Novosyn CHD
Sterile synthetic resorbable Suture with antibacterial multifilament with the following parameters:
Suture Sizes (diameters): USP 5/0 (metric 1) up to USP 2 (metric 5)
Suture lengths :45-150 cm
Color: violet colored / undyed

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