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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

B. Braun Medical Inc.
824 Twelfth Avenue
18018 BETHLEHEM
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	713332156 / US-200210004786	NAM-Audit@tuvsud.com		2024-06-26	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 044904 0058 Rev. 02

Reference: 713332156

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: US-MF-000011193

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 3 identifies the devices for which an MDR certificate already exists.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 044904 0058 Rev. 02

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
204-06-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Ulrike Martin
Ulrike Martin (26. Juni 2024 12:35 GMT+2)

Ulrike Martin
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias Mumme
Matthias Mumme (26. Juni 2024 11:28 GMT+2)

Claus Matthias Mumme
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Caresite® Luer Access Device	415122	☑ N/A	40392390000028463D	☑ Class IIa	☑ Certification as follows: G1 044904 0052; NB0123
Caresite® Luer Access Device (export only)	415122-01				
Caresite® Smallbore Extension Set	470100				
Caresite® Smallbore Extension Set (export only)	470100-01				
Caresite® Smallbore Y-Extension Set	470106				
Caresite® Smallbore Y-Extension Set (export only)	470106-01				
Caresite® Extension Set	470108				
Caresite® Extension Set (export only)	470108-01				
Caresite® Smallbore Triple Extension Set (export only)	470160				
Caresite® Smallbore Triple Extension Set (export only)	470161				
Caresite® Smallbore Double Extension Set	470182				
Caresite® Extension Set (export only)	470183				
Caresite® Bifurcated Extension Set (export only)	470200-01				
Winged Infusion Set	7B3050	☑ N/A	40392390000029933T	☑ Class IIa	☑ Certification as follows: G1 044904 0052; NB0123
Normally Closed Backcheck Valve	415062	☑ N/A	40392390000028453B	☑ Class I devices in sterile condition	☑ Certification as follows: G2S 044904 0051; NB0123
Safsite Injection Site and Cap	415068				
Smallbore T-Port Extension Set	471950 471954				
Mini-Spike Dispensing Pin	412000	☑ N/A	403923900000290000	☑ Class I devices in sterile condition	☑ Certification as follows: G2S 044904 0051; NB0123
Mini-Spike (vented) Dispensing Pin	412012				
Dispensing Pin	412006 412014 413501				
Transfer Needle - Double Ended, Non-Filtered	415017				

Micro-Pin	415019	☑ N/A	403923900000290000	☑ Class I devices in sterile condition	☑ Certification as follows: G2S 044904 0051; NB0123
Filter Needle	415030				
Vented Needle, Lateral Flow	415072				
Fluid Dispensing Connector	415080				
Tamper-Evident Cap	418004				
Multi-Ad Luer Lock Syringe Cap	418012 418013				
Flexible Syringe Cap	418200 418202				
Multi-Ad Fluid Dispensing System	513506				
Multi-Ad Fluid Transfer Set	513548				
Dual Spike Transfer Device	7A3261				
BSS Plus Sterile Vacuum Transfer Device	7A3814				
26-Lead Transfer Set for use with APEX Compounding System	2112650				
Filter Needle	415040	4550404			
Filter Hub	418021	4551001			
Filter Straw	415020 415021	4550200 4550250			
Sterifix® Filter Straw 4" Sterifix® Filter Straw 1.75"	339171 339170	4550200N 4550250N	403923900000290000	☑ Class I devices in sterile condition	☑ Certification as follows: G2S 012974 0457[1]; NB0123
Sterifix® Filter Needle 1.5"	339169	4550404N			
Safety Introducer Needle	613105 613106 613201 613204 613443 613444 613445 613446	☑ N/A	40392390000017612V	☑ Class IIa	☑ Certification MDD: G1 044904 0052; MDR Certificate: G10 044904 0057 NB0123
Inflation device	622510	☑ N/A	40392390000017602T	☑ Class I devices in sterile condition	☑ Certification MDD: G2S 044904 0051; MDR Certificate: G11 044904 0056; NB0123

[1] According to the document “Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607” (Rev. 1, July 2023), where the manufacturer certified under the MDD/AIMDD transfers device(s) covered by those MDD/AIMDD certificate(s) to another manufacturer who intends to place those device(s) on the market under the MDR, this is only possible if the manufacturer indicated on the MDD/AIMDD certificate and the manufacturer seeking MDR certification are part of the same larger organization.

This is the case for B. Braun medical Inc. and B. Braun Melsungen AG (Germany) and applies for the Basic UDI-DI 403923900000290000 for which B. Braun Medical Inc. will be the new Legal Manufacturer under MDR.

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-11	713332156	Initial AR
2024-05-13	713332156_2 / US-200210004786	Addition of MDR certified devices to table 1
2024-05-15	713332156_2 / US-200210004786	Correction of MDD article numbers for BUDI 403923900000290000
2024-06-12	713332156_4	Correction: Filter Needle, - Hub & - Straw added to MDD cert. G2S 044904 0051 instead of G2S 012974 0457