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

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
12974	713316029 / 71323653/ 71332278 / 713263785 / 713303196 / 713257209	medical_devices@tuvsud.com	N/A	2024-04-30	1 of 13

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0656 Rev. 01**

Reference: 713316029 / 71323653/ 71332278 / 713263785 / 713303196 / 713257209

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:

SRN Number: DE-MF-000000201

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
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VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

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Certification body for medical Products
Ridlerstr. 65
80339 Munich
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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=CL_012974_0656_Rev._01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

12th April 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read 'J. Kunte', written over a light blue horizontal line.

SIGN-ID 607855
30.04.2024
Jürgen Kunte

Conformity Assessment Responsible (CARE)

Tunde Junaid
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
Perifix® Catheter	4513150	N/A	40392390000023832S	Class III	G1 012974 0607 Rev. 02; G7 012974 0612 Rev. 00; NB0123
Perifix® Catheter	4513258				
Perifix® Catheter	4513177				
Perifix® SoftTip Catheter	4515048				
Perifix® Catheter NRFit®	4513258N-01				
Perifix® Catheter NRFit®	4513150N-01				
Perifix® Catheter NRFit®	4513177N-01				
Perifix® SoftTip Catheter NRFit®	4515048N-01				
Perifix® ONE Catheter	4513150C				
Perifix® ONE Catheter	4513258C				
Perifix® ONE Catheter NRFit®	45132581N-01				
Perifix® ONE Catheter NRFit®	45131501N-01				
Perifix 400	4514009	N/A	40392390000023842U	Class III	G1 012974 0607 Rev. 02; G7 012974 0612 Rev. 00; NB0123
Perifix 401	4514017				
Perifix 402	4514025				
Perifix 451	4514513				
Perifix Soft Tip 701	4510097				
Perifix Soft Tip 700	4510216				
Perifix Soft Tip 730	4517309				
Perifix Soft Tip 750	4517504				
Perifix 100	4511000				
Perifix 300	4513002				
Perifix 301	4513010				
Perifix 302	4513029				
Perifix 310	4513100				
Perifix 400 NRFit	4514009N-01				
Perifix 401 NRFit	4514017N-01				
Perifix 402 NRFit	4514025N-01				
Perifix Soft Tip 701 NRFit	4510097N-01				
Perifix Soft Tip 730 NRFit	4517309N-01				
Perifix 300 NRFit	4513002N-01				
Perifix ONE 400	4514009C				
Perifix ONE 401	4514017C				
Perifix ONE 402	4514025C				



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
Perifix ONE 418	4514183C				
Perifix ONE 451	4514513C				
Perifix ONE 401 NRFit	45140171N-01				
Perifix ONE 402 NRFit	45140251N-01				
Perifix 420	4514203				
Perifix 421	4514211				
Perifix 430	4514300				
Perifix 431	4514319				
Perifix 620	4516206				
Perifix Soft Tip 900	4510291				
Perifix Soft Tip 901	4510305				
Perifix 421 NRFit	4514211N-01				
Perifix Soft Tip 901 NRFit	4510305N-01				
Perifix ONE 420	4514203C				
Perifix ONE 421	4514211C				
Perifix ONE 431	4514319C				
Perifix ONE Paed Set 18	4512006C				
Perifix ONE Paed Set 20	4512014C				
Perifix ONE 421 NRFit	45142111N-01				
Perifix ONE Paed Set 18 NRFit	45120061N-01				
Perifix ONE Paed Set 20 NRFit	45120141N-01				
Espocan	4556674	N/A	40392390000023862Y	Class III	G1 012974 0607 Rev. 02; G7 012974 0612 Rev. 00; NB0123
Espocan	4556666				
Espocan with Docking System	4556747				
Espocan with Docking System	4556763				
Espocan NRFit	4556674N-01				
Espocan NRFit	4556666N-01				
Espocan NRFit with Docking System	4556747N-01				
Espocan NRFit with Docking System	4556763N-01				
Certofix® Mono Paed S 110	4160177	N/A	40392390000007422J	Class III	G1 012974 0607 Rev. 02; G7 012974 0593 Rev. 01;
Certofix® Mono Paed S 110	4160177-01				
Certofix® Mono Paed S 110	4160177-04				
Certofix® Mono S 215	4160185				



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
Certofix® Mono S 215	4160185-07				NB0123
Certofix® Mono 215	4160185E				
Certofix® Mono 215	4160185E-07				
Certofix® Mono S 220	4160207				
Certofix® Mono S 220	4160207-07				
Certofix® Mono 220	4160207E				
Certofix® Mono 220	4160207E-07				
Certofix® Mono 220 R	4160207R				
Certofix® Mono V 220	4160215				
Certofix® Mono V 220	4160215-07				
Certofix® Mono S 315	4160223				
Certofix® Mono S 315	4160223-07				
Certofix® Mono 315	4160223E				
Certofix® Mono 315	4160223E-07				
Certofix® Mono V 315	4160231				
Certofix® Mono V 315	4160231-07				
Certofix® Mono S 320	4160258				
Certofix® Mono S 320	4160258-07				
Certofix® Mono 320	4160258E				
Certofix® Mono 320	4160258E-07				
Certofix® Mono 320 R	4160258R				
Certofix® Safety Mono S 320	4160258S				
Certofix® Safety Mono S 320	4160258S-07				
Certofix® Mono V 320	4160266				
Certofix® Mono V 320	4160266-07				
Certofix® Mono S 330	4160282				
Certofix® Mono S 330	4160282-07				
Certofix® Mono 330	4160282E				
Certofix® Mono 330	4160282E-07				
Certofix® Safety Mono S 330	4160282S				
Certofix® Safety Mono S 330	4160282S-07				
Certofix® Mono V 330	4160290				
Certofix® Mono V 330	4160290-07				
Certofix® Mono S 420	4160304				
Certofix® Mono S 420	4160304-07				
Certofix® Mono 420	4160304E				
Certofix® Mono 420	4160304E-07				
Certofix® Mono 420 R	4160304R				
Certofix® Mono V 420	4160320				
Certofix® Mono V 420	4160320-07				
Certofix® Mono S 415	4160509				
Certofix® Mono S 415	4160509-07				



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Certofix® Mono 415	4160509E				
Certofix® Mono 415	4160509E-07				
Certofix® Mono V 415	4160517				
Certofix® Mono V 415	4160517-07				
Certofix® Trio HF S 1215	4160578				
Certofix® Trio HF S 1215	4160578-07				
Certofix® Trio HF S 1220	4160586				
Certofix® Trio HF S 1220	4160586-07				
Certofix® Trio HF V 1215	4160614				
Certofix® Trio HF V 1215	4160614-07				
Certofix® Trio HF V 1220	4160622				
Certofix® Trio HF V 1220	4160622-07				
Certofix® Mono S 430	4160762				
Certofix® Mono S 430	4160762-07				
Certofix® Mono 430	4160762E				
Certofix® Mono 430	4160762E-07				
Certofix® Mono V 430	4160789				
Certofix® Mono V 430	4160789-07				
Certofix® Trio 715	4161157E				
Certofix® Trio 715	4161157E-07				
Certofix® Trio S 715	4161159				
Certofix® Trio S 715	4161159-07				
Certofix® Duo V 720	4161211				
Certofix® Duo V 720	4161211-07				
Certofix® Duo V 730	4161319				
Certofix® Duo V 730	4161319-07				
Certofix® Trio V 715	4162153				
Certofix® Trio V 715	4162153-07				
Certofix® Duo 720	4162200E				
Certofix® Duo 720	4162200E-07				
Certofix® Duo 730	4162307E				
Certofix® Duo 730	4162307E-07				
Certofix® Trio 720	4163206E				
Certofix® Trio 720	4163206E-07				
Certofix® Trio V 720	4163214				
Certofix® Trio V 720	4163214-07				
Certofix® Trio 730	4163303E				
Certofix® Trio 730	4163303E-07				
Certofix® Trio S 730	4163306				
Certofix® Trio S 730	4163306-07				
Certofix® Safety Trio S 730	4163306S				
Certofix® Safety Trio S 730	4163306S-07				



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Certofix® Trio V 730	4163311				
Certofix® Trio V 730	4163311-07				
Certofix® Duo 715	4164156E				
Certofix® Duo 715	4164156E-07				
Certofix® Duo S 715	4164158				
Certofix® Duo S 715	4164158-07				
Certofix® Duo V 715	4166159				
Certofix® Duo V 715	4166159-07				
Certofix® Quinto V 1215	4166841				
Certofix® Quinto V 1215	4166841-07				
Certofix® Quinto S 1220	4166852				
Certofix® Quinto S 1220	4166852-07				
Certofix® Safety Quinto S 1220	4166852S				
Certofix® Safety Quinto S 1220	4166852S-07				
Certofix® Quinto V 1220	4166868				
Certofix® Quinto V 1220	4166868-07				
Certofix® Duo Paed S 408	4166906				
Certofix® Duo Paed S 408	4166906-07				
Certofix® Duo Paed S 413	4166922				
Certofix® Duo Paed S 413	4166922-07				
Certofix® Duo Paed S 420	4166949				
Certofix® Duo Paed S 420	4166949-07				
Certofix® Duo Paed S 508	4167112				
Certofix® Duo Paed S 508	4167112-07				
Certofix® Duo Paed S 513	4167139				
Certofix® Duo Paed S 513	4167139-07				
Certofix® Duo Paed S 520	4167155				
Certofix® Duo Paed S 520	4167155-07				
Certofix® Trio Paed S 508	4167228				
Certofix® Trio Paed S 508	4167228-07				
Certofix® Trio Paed S 513	4167244				
Certofix® Trio Paed S 513	4167244-07				
Certofix® Trio Paed S 520	4167260				
Certofix® Trio Paed S 520	4167260-07				
Certofix® Duo S 720	4167385				
Certofix® Duo S 720	4167385-07				
Certofix® Safety Duo S 720	4167385S				
Certofix® Safety Duo S 720	4167385S-07				
Certofix® Duo S 730	4167394				
Certofix® Duo S 730	4167394-07				



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Certofix® Safety Duo S 730	4167394S				
Certofix® Safety Duo S 730	4167394S-07				
Certofix® Trio S 720	4167408				
Certofix® Trio S 720	4167408-07				
Certofix® Safety Trio S 720	4167408S				
Certofix® Safety Trio S 720	4167408S-07				
Certofix® Duo HF V 920	4167511				
Certofix® Duo HF V 920	4167511-07				
Certofix® Duo HF V 1215	4167538				
Certofix® Duo HF V 1215	4167538-07				
Certofix® Duo HF V 1220	4167546				
Certofix® Duo HF V 1220	4167546-07				
Certofix® Quattro V 815	4167767				
Certofix® Quattro V 815	4167767-07				
Certofix® Quattro V 820	4167775				
Certofix® Quattro V 820	4167775-07				
Certofix® Safety Quattro V 820	4167775S				
Certofix® Safety Quattro V 820	4167775S-07				
Certofix® Quattro V 830	4167783				
Certofix® Quattro V 830	4167783-07				
Certofix® Duo HF V 715	4168518				
Certofix® Duo HF V 715	4168518-07				
Certofix® Duo HF S 720	4168528				
Certofix® Duo HF S 720	4168528-07				
Certofix® Duo HF V 720	4168534				
Certofix® Duo HF V 720	4168534-07				
Certofix® protect Mono V 320	4160266P	N/A	40392390000025883E	Class III	G1 012974 0607 Rev. 02; G7 012974 0593 Rev. 01; NB0123
Certofix® protect Mono V 320	4160266P-07				
Certofix® protect Mono V 330	4160290P				
Certofix® protect Mono V 330	4160290P-07				
Certofix® protect Mono V 420	4160320P				
Certofix® protect Mono V 420	4160320P-07				
Certofix® protect Trio HF V 1220	4160622P				
Certofix® protect Trio HF V 1220	4160622P-07				
Certofix® protect Mono V 430	4160789P				
Certofix® protect Mono V 430	4160789P-07				
Certofix® protect Duo V 720	4161211P				
Certofix® protect Duo V 720	4161211P-07				



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
Certofix® protect Duo V 730	4161319P				
Certofix® protect Duo V 730	4161319P-07				
Certofix® protect Trio V 715	4162153P				
Certofix® protect Trio V 715	4162153P-07				
Certofix® protect Trio V 720	4163214P				
Certofix® protect Trio V 720	4163214P-07				
Certofix® protect Trio V 730	4163311P				
Certofix® protect Trio V 730	4163311P-07				
Certofix® protect Duo V 715	4166159P				
Certofix® protect Duo V 715	4166159P-07				
Certofix® protect Quinto V 1220	4166868P				
Certofix® protect Quinto V 1220	4166868P-07				
Certofix® protect Quattro V 815	4167767P				
Certofix® protect Quattro V 815	4167767P-07				
Certofix® protect Quattro V 820	4167775P				
Certofix® protect Quattro V 820	4167775P-07				
Certofix® protect Quattro V 830	4167783P				
Certofix® protect Quattro V 830	4167783P-07				
Certofix® protect Duo HF V 720	4168534P				
Certofix® protect Duo HF V 720	4168534P-07				
Spinocan®	4521801	4501373 4501390	4039239000008612T	Class III	G1 012974 0607 rev. 02; G7 012974 0592 rev. 02; NB0123
Spinocan®	4522001	4509757 4509900			
Spinocan®	4522201	4507401			
Spinocan®	4522202	4507754			
Spinocan®	4522203	4507908			
Spinocan®	4522204	4506090			
Spinocan®	4522501	4505751			
Spinocan®	4522502	4505905			
Spinocan®	4522503	4505913			
Spinocan®	4522601	4502906			



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
		4504917			
Spinocan®	4522701	4503902			
Spinocan®	4522702	4502140			
Spinocan®	4522703	4501900			
Spinocan®	4522901	4501918			
Pencan	4532201	4502035			
Pencan	4532501	4502167			
Pencan	4532502	4502159			
Pencan	4532503	4502019			
Pencan	4532504	4502043			
Pencan	4532506	4502116			
Pencan	4532701	4502175			
Pencan	4532702	4502027			
Pencan	4532703	4502051			
Pencan	4532705	4502124			
Pencan	4532706	4502132			
Atraucan®	4542601	4504771			
Atraucan®	4542602	4504763			
Atraucan®	4542603	4504739			
Spinocan®	4521801N	4501390N-01 4501373N-01			
Spinocan®	4522001N	4509757N-01 4509900N-01			
Spinocan®	4522201N	4507401N-01			
Spinocan®	4522202N	4507754N-01			
Spinocan®	4522203N	4507908N-01			
Spinocan®	4522204N	4506090N-01 4506095N-01			
Spinocan®	4522501N	4505751N-01			
Spinocan®	4522502N	4505905N-01			
Spinocan®	4522503N	4505913N-01			
Spinocan®	4522601N	4502906N-01 4504917N-01			
Spinocan®	4522701N	4503902N-01			
Spinocan®	4522702N	4502140N-01			
Spinocan®	4522901N	4501900N-01 4501901N-01 4501918N-01			
Pencan	4532201N	4502035N-01			
Pencan	4532501N	4502167N-01			
Pencan	4532502N	4502159N-01			
Pencan	4532503N	4502019N-01			



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
Pencan	4532504N	4502043N-01 4502044N-01			
Pencan	4532506N	4502116N-01 4502117N-01			
Pencan	4532507N	4502120N-01			
Pencan	4532510N	333877N-01			
Pencan	4532701N	4502175N-01			
Pencan	4532702N	4502027N-01			
Pencan	4532703N	4502051N-01 4502052N-01			
Pencan	4532705N	4502124N-01 4502125N-01			
Pencan	4532706N	4502132N-01			
Pencan	4502035-13	N/A	403923900000085938	Class III	G1 012974 0607 rev. 02; G7 012974 0592 rev. 02; NB0123
Pencan	4502167-13				
Pencan	4502159-13				
Pencan	4502019-01				
Pencan	4502019-10				
Pencan	4502043-13				
Pencan	4502116-13				
Pencan	4502120-13				
Pencan	4502175-13				
Pencan	4502027-01				
Pencan	4502027-10				
Pencan	4502051-13				
Pencan	4502124-13				
Pencan	4502132-13				
Spinocan®	4501373-13				
Spinocan®	4501390-01				
Spinocan®	4501390-10				
Spinocan®	4501144-13	4501144			
Spinocan®	4501195-13	4501195			
Spinocan®	4509757-13	N/A			
Spinocan®	4509900-01				
Spinocan®	4509900-10				
Spinocan®	4507401-13				
Spinocan®	4507754-13				
Spinocan®	4507908-01				
Spinocan®	4507908-10				
Spinocan®	4506090-13				
Spinocan®	4506014-03				
Spinocan®	4505751-01				



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Spinocan®	4505751-10				
Spinocan®	4505905-01				
Spinocan®	4505905-10				
Spinocan®	4505913-13				
Spinocan®	4502906-01				
Spinocan®	4502906-10				
Spinocan®	4504917-13				
Spinocan®	4503902-01				
Spinocan®	4503902-10				
Spinocan®	4502140-13				
Spinocan®	4501900-13				
Spinocan®	4501918-13				
Perican	4512453	N/A	40392390000023912R	Class III	G1 012974 0607 Rev. 02; G7 012974 0612 Rev. 00; NB0123
Perican	4512200				
Perican	4512383				
Perican	4512588				
Perican	4512782				
Perican Paed	4502078				
Perican Paed	4502094				
Perican Paed	4502302				
Perican NRFit	4512383N-01				
Perican NRFit	4512200N-01				
Perican NRFit	4512782N-01				
Perican NRFit	4512453N-01				
Perican NRFit	4512785N-01				
Perican NRFit	4512784N-01				
Perican Paed NRFit	4502078N-01				
Perican Paed NRFit	4502094N-01				
Perican Paed NRFit	4502302N-01				
Epican Paed	4502400	N/A	40392390000027953M	Class III	G1 012974 0607 Rev. 02; G7 012974 0612 Rev. 00; NB0123
Epican Paed	4502418				
Epican Paed	4502426				
Epican Paed NRFit	4502400N-01				
Epican Paed NRFit	4502418N-01				
Epican Paed NRFit	4502426N-01				



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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/12	713316029 / 71323653 / 71332278 / 713263785 / 713303196 / 713257209	Initial issue
2024/04/30	713316029 / 71323653 / 71332278 / 713263785 / 713303196 / 713257209	Second Issue (Revision 1): Addition of additional article codes: 4501144 and 4501195 (Spinocan® substitute Article no).