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TÜV SÜD Product Service GmbH · Germany

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78532 Tuttlingen
GERMANY

Your reference/letter of	Our reference	Email	Fax extension	Date	Page
49044	713337717 713344242 713343811	medical_devices@tuvsud.com	-	2024-08-07	1 of 288

**TÜV SÜD Product Service GmbH
Confirmation Letter**

CL 049044 0018 Rev. 00

Reference: 713337717 | 713344242 | 713343811

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: DE-MF-000009286

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
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Information pursuant to § 2 [1] DL-InfoV
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Supervisory Board:
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Board of Management:
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Patrick van Welij

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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_049044_0018

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-07

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services


[Franziska Biedermann \(8. August 2024 09:16 GMT+2\)](#)

Franziska Biedermann
Conformity Assessment Responsible (CARE)



Franziska Eckert
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 or Basic UDI-DI (under MDR appli- cation)	MDR Device classifi- cation (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification																																		
Device 1 Basic UDI-DI: 04058368051L030101E4 <table><tr><td>Buie Rektal-Absaugrohr, mit Unterbrecherloch</td><td>HB1245-01</td></tr><tr><td>Buie Rektal-Absaugrohr, 5mm,</td><td>HB1245-02</td></tr><tr><td>Triport (Fournier) Fettabsaugungskanüle, Griffansatz, Ø3mm, 25cm</td><td>HB2590-53</td></tr><tr><td>Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 20cm</td><td>HB2591-43</td></tr><tr><td>Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø4mm, 20cm</td><td>HB2591-44</td></tr><tr><td>Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 25cm</td><td>HB2591-53</td></tr><tr><td>Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø5mm, 30cm</td><td>HB2591-65</td></tr><tr><td>Monoport Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm</td><td>HB2592-33</td></tr><tr><td>Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø2mm, 10cm</td><td>HB2593-22</td></tr><tr><td>Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø3mm, 15cm</td><td>HB2593-33</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø2mm, 5cm</td><td>HB2594-12</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm</td><td>HB2594-33</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø4mm, 25cm</td><td>HB2594-54</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 30cm</td><td>HB2594-63</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø5mm, 30cm</td><td>HB2594-65</td></tr><tr><td>Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø6mm, 30cm</td><td>HB2594-66</td></tr><tr><td>Mercedes Fettabsaugungskanüle, Griffansatz, Ø2mm, 15cm</td><td>HB2596-32</td></tr></table>	Buie Rektal-Absaugrohr, mit Unterbrecherloch	HB1245-01	Buie Rektal-Absaugrohr, 5mm,	HB1245-02	Triport (Fournier) Fettabsaugungskanüle, Griffansatz, Ø3mm, 25cm	HB2590-53	Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 20cm	HB2591-43	Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø4mm, 20cm	HB2591-44	Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 25cm	HB2591-53	Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø5mm, 30cm	HB2591-65	Monoport Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm	HB2592-33	Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø2mm, 10cm	HB2593-22	Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø3mm, 15cm	HB2593-33	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø2mm, 5cm	HB2594-12	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm	HB2594-33	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø4mm, 25cm	HB2594-54	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 30cm	HB2594-63	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø5mm, 30cm	HB2594-65	Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø6mm, 30cm	HB2594-66	Mercedes Fettabsaugungskanüle, Griffansatz, Ø2mm, 15cm	HB2596-32	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☐ Class IIb / Class IIb implantable (ex- empted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Buie Rektal-Absaugrohr, mit Unterbrecherloch	HB1245-01																																				
Buie Rektal-Absaugrohr, 5mm,	HB1245-02																																				
Triport (Fournier) Fettabsaugungskanüle, Griffansatz, Ø3mm, 25cm	HB2590-53																																				
Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 20cm	HB2591-43																																				
Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø4mm, 20cm	HB2591-44																																				
Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø3mm, 25cm	HB2591-53																																				
Triport (Fournier) Fettabsaugungsk., Luer Lock-Ansatz, Ø5mm, 30cm	HB2591-65																																				
Monoport Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm	HB2592-33																																				
Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø2mm, 10cm	HB2593-22																																				
Monoport Fettabsaugungskanüle, Luer Lock-Ansatz, Ø3mm, 15cm	HB2593-33																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø2mm, 5cm	HB2594-12																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 15cm	HB2594-33																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø4mm, 25cm	HB2594-54																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø3mm, 30cm	HB2594-63																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø5mm, 30cm	HB2594-65																																				
Toledeo (Shark) Fettabsaugungskanüle, Griffansatz, Ø6mm, 30cm	HB2594-66																																				
Mercedes Fettabsaugungskanüle, Griffansatz, Ø2mm, 15cm	HB2596-32																																				



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
Mercedes Fettabsaugungskannüle, Griffansatz, Ø3mm, 15cm	HB2596-33			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø3mm, 15cm	HB2596-34			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø3mm, 25cm	HB2596-53			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø4mm, 25cm	HB2596-54			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø5mm, 25cm	HB2596-55			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø3mm, 30cm	HB2596-63			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø4mm, 30cm	HB2596-64			
Mercedes Fettabsaugungskannüle, Griffansatz, Ø5mm, 30cm	HB2596-65			
Mercedes Fettabsaugungskannüle, Luer Lock-Ansatz, Ø4mm, 20cm	HB2597-44			
Mercedes Fettabsaugungskannüle, Luer Lock-Ansatz, Ø4mm, 25cm	HB2597-54			
Mercedes Fettabsaugungskannüle, Luer Lock-Ansatz, Ø4mm, 30cm	HB2597-64			
Mercedes Fettabsaugungskannüle, Luer Lock-Ansatz, Ø5mm, 30cm	HB2597-65			
Saugrohr Fukushima-St., Ch3	HB2665-03			
Saugrohr Fukushima-St., Ch4	HB2665-04			
Saugrohr Fukushima-St., Ch5	HB2665-05			
Saugrohr Fukushima-St., Ch6	HB2665-06			
Saugrohr Fukushima-St., Ch7	HB2665-07			
Saugrohr Fukushima-St., Ch8	HB2665-08			
Saugrohr Fukushima-St., Ch9	HB2665-09			
Saugrohr Fukushima-St., Ch10	HB2665-10			
Saugrohr Fukushima-St., Ch11	HB2665-11			
Saugrohr Fukushima-St., Ch12	HB2665-12			
Saugrohr Fukushima-St., Ch. 3, Arbeitslänge 115mm, 18cm	HB2665-13			
Saugrohr Fukushima-St., Ch4	HB2665-14			
Saugrohr Fukushima-St., Ch5	HB2665-15			
Saugrohr Fukushima-St., Ch6	HB2665-16			
Saugrohr Fukushima-St., Ch7	HB2665-17			
Saugrohr Fukushima-St., Ch8	HB2665-18			



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
Saugrohr, Fukushima-Style,	HB2665-19			
Saugrohr Fukushima-St., Ch. 10, Arbeitslänge 115mm, 18cm	HB2665-20			
Saugrohr Fukushima-St., Ch12	HB2665-22			
Saugrohr Fukushima-St., Ch. 3, Arbeitslänge 140mm, 20,5cm	HB2665-23			
Saugrohr Fukushima-St., Ch4	HB2665-24			
Saugrohr Fukushima-St., Ch5	HB2665-25			
Saugrohr Fukushima-St., Ch6	HB2665-26			
Saugrohr Fukushima-St., Ch7	HB2665-27			
Saugrohr Fukushima-St., Ch8	HB2665-28			
Saugrohr Fukushima-St., Ch9	HB2665-29			
Saugrohr Fukushima-St., Ch10	HB2665-30			
Saugrohr Fukushima-St., Ch12	HB2665-32			
Saugrohr Fukushima-St., Ch3,	HB2665-33			
Saugrohr Fukushima-St., Ch4	HB2665-34			
Saugrohr Fukushima-St., Ch5	HB2665-35			
Saugrohr Fukushima-St., Ch6	HB2665-36			
Saugrohr Fukushima-St., Ch7	HB2665-37			
Saugrohr Fukushima-St., Ch8	HB2665-38			
Saugrohr Fukushima-St., Ch9	HB2665-39			
Saugrohr Fukushima-St., Ch. 10, Arbeitslänge 165mm, 23cm	HB2665-40			
Saugrohr Fukushima-St., Ch12	HB2665-42			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-00			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-05			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-07			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-10			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-15			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-17			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-20			
Rhoton-Merz Saugrohr, abgewinkelt, 12FR, 8,5cm	HB2667-22			
Saugrohr, Rhoton-Merz-Style, abgewinkelt, Ø1,0mm, 85mm	HB2667-23			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-25			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-27			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-30			



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
Rhoton-Merz Saugrohr, 50° abgewinkelt, 12FR, 10,0cm	HB2667-32			
Saugrohr, Rhoton-Merz-Style, CH3, gebogen, Arbeitslänge 100mm	HB2667-33			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-35			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-37			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-40			
Rhoton-Merz Saugrohr, abgewinkelt, 12FR, 13,0cm	HB2667-42			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-45			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-47			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-50			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-55			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-57			
Saugrohr, Rhoton-Merz-St. Ch10	HB2667-60			
Saugrohr, Rhoton-Merz-St. Ch5	HB2667-65			
Saugrohr, Rhoton-Merz-St. Ch7	HB2667-67			
Strauss Saugkanüle, 12,5cm	HB2668-00			
Antonius Saugrohr, 4mm	HB2668-04			
Antonius Saugrohr, 8mm	HB2668-08			
Adson Saugrohr, CH12, 21cm	HB2668-12			
Dawson-Yuhl Saugrohr, 13Fr, 27,9cm	HB2668-13			
Adson Saugrohr, CH15, 21cm	HB2668-15			
Rosen Saugrohr, 18GA, gewinkelt, Gesamtlänge 8,5cm	HB2668-18			
Rosen Saugrohr, 20GA, gewinkelt, Gesamtlänge 8,5cm	HB2668-20			
Rosen Saugrohr, 22GA, gewinkelt, Gesamtlänge 8,5cm	HB2668-22			
House Saugrohr, 18GA, mit Obturator	HB2668-38			
House Saugrohr, 20GA, mit Obturator	HB2668-40			
House Saugrohr, 22GA, mit Obturator	HB2668-42			
Wullstein Mikro-Absaugrohr kp.	HB2669.			
Wullstein Mikro-Absaugrohr,	HB2669-00			
Wullstein Mikro-Saugkanüle	HB2669-05			
Wullstein Mikro-Saugkanüle	HB2669-07			
Wullstein Mikro-Saugkanüle	HB2669-10			



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
Wullstein Mikro-Saugkanüle	HB2669-12			
Set: Zöllner Sauger, 2 Kanülen	HB2669-20.			
Zöllner Saugrohr	HB2669-21			
Zöllner Saugkanüle allein	HB2669-27			
Zöllner Saugkanüle allein	HB2669-29			
Frazier Saugrohr, 5CH, 45°, 90mm	HB2669-85			
Frazier Saugrohr, 6CH, 45°, 90mm	HB2669-86			
Frazier Saugrohr, 7CH, 45°, 90mm	HB2669-87			
Frazier Saugrohr, 8CH, 45°, 90mm	HB2669-88			
Frazier Saugrohr, 9CH, 45°, 90mm	HB2669-89			
Frazier Saugrohr, 10CH, 45°, 90mm	HB2669-90			
Frazier Saugrohr, 11CH, 45°, 90mm	HB2669-91			
Frazier Saugrohr, 12CH, 45°, 90mm	HB2669-92			
Frazier Saugrohr, 15CH, 45°, 90mm	HB2669-95			
Frazier Saugrohr, 3CH, 11cm	HB2670-03			
Frazier Saugrohr, 4CH, 11cm	HB2670-04			
Frazier Saugrohr, 5CH, 18cm	HB2670-05			
Frazier Saugrohr, 6CH, 18cm	HB2670-06			
Frazier Saugrohr, 7CH, 18cm	HB2670-07			
Frazier Saugrohr, 7CH, 45°, 110mm, isoliert	HB2670-07L			
Frazier Saugrohr, 8CH, 18cm	HB2670-08			
Frazier Saugrohr, 9CH, 18cm	HB2670-09			
Frazier Saugrohr, 10CH, 18cm	HB2670-10			
Frazier Saugrohr, 10CH, 45°, 110mm, isoliert	HB2670-10L			
Frazier Saugrohr, 11CH, 18cm	HB2670-11			
Frazier Saugrohr, 12CH, 18cm	HB2670-12			
Frazier Saugrohr, 12CH, 45°, 110mm, isoliert	HB2670-12L			
Frazier Saugrohr, 14CH, 11cm	HB2670-14			
Frazier Saugrohr, 15CH, 18cm	HB2670-15			
Frazier Saugrohr, 5CH, 18cm	HB2670-25			
Frazier Saugrohr, 6CH, 18cm	HB2670-26			
Frazier Saugrohr, 7CH, 45°, 130mm	HB2670-27			
Frazier Saugrohr, 8CH, 18cm	HB2670-28			
Frazier Saugrohr, 9CH, 18cm	HB2670-29			
Frazier Saugrohr, 10CH, 45°, 130mm	HB2670-30			
Frazier Saugrohr, 11CH, 45°, 130mm	HB2670-31			



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
Frazier Saugrohr, 12CH, 18cm	HB2670-32			
Frazier Saugrohr, 15CH, 18cm	HB2670-35			
Frazier Saugrohr, 5CH, 18cm	HB2670-45			
Frazier Saugrohr, 6CH, 18cm	HB2670-46			
Frazier Saugrohr, 7CH, 45°, 160mm	HB2670-47			
Frazier Saugrohr, 8CH, 18cm	HB2670-48			
Frazier Saugrohr, 9CH, 18cm	HB2670-49			
Frazier Saugrohr, 10CH, 45°, 160mm	HB2670-50			
Frazier Saugrohr, 11CH, 45°, 160mm	HB2670-51			
Frazier Saugrohr, 12CH, 18cm	HB2670-52			
Frazier Saugrohr, 15CH, 18cm	HB2670-55			
Frazier Saugrohr, 5CH, 20cm	HB2670-65			
Frazier Saugrohr, 6CH, 20cm	HB2670-66			
Frazier Saugrohr, 7CH, 20cm	HB2670-67			
Frazier Saugrohr, 8CH, 20cm	HB2670-68			
Frazier Saugrohr, 9CH, 20cm	HB2670-69			
Frazier Saugrohr, 10CH, 20cm	HB2670-70			
Frazier Saugrohr, 11CH, 20cm	HB2670-71			
Frazier Saugrohr, 12CH, 20cm	HB2670-72			
Frazier Saugrohr, 14CH, 45°, 19,1cm	HB2670-74			
Frazier Saugrohr, 15CH, 20cm	HB2670-75			
Frazier Saugrohr, 6CH, 18cm	HB2670-86			
Frazier Saugrohr, 7CH, 18cm	HB2670-87			
Frazier Saugrohr, 8CH, 18cm	HB2670-88			
Frazier Saugrohr, 9CH, 18cm	HB2670-89			
Frazier Saugrohr, 10CH, 18cm	HB2670-90			
Frazier Saugrohr, 11CH, 18cm	HB2670-91			
Frazier Saugrohr, 12CH, 18cm	HB2670-92			
Frazier Saugrohr, 15CH, 18cm	HB2670-95			
Ferguson Saugrohr, 6CH, 2mm,	HB2672-06			
Ferguson Saugrohr, 7CH,	HB2672-07			
Ferguson Saugrohr, 8CH,	HB2672-08			
Ferguson Saugrohr, 9CH, 3mm,	HB2672-09			
Ferguson Saugrohr, 10 CH,	HB2672-10			
Ferguson Saugrohr, 11CH,	HB2672-11			
Ferguson Saugrohr, 12CH,	HB2672-12			
Ferguson-Frazier Saugrohr, 14CH, 102mm	HB2672-14			
Ferguson Saugrohr, 15CH,	HB2672-15			
Frazier-Paparella Saugrohr, 7Fr, Nr. 1, Arbeitslänge 5,7cm	HB2672-17			



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
Frazier-Paparella Saugrohr, 10Fr, Nr. 1, Arbeitslänge 5,7cm	HB2672-20			
Brochman Saugrohr, 5Fr, Arbeitslänge 10,2cm	HB2672-25			
Brochman Saugrohr, 7Fr, Arbeitslänge 10,2cm	HB2672-27			
Plester Saugrohr, 5CH, 19,5cm	HB2673-05			
Plester Saugrohr, 6CH, 19,5cm	HB2673-06			
Plester Saugrohr, 7CH, 19,5cm	HB2673-07			
Plester Saugrohr, 8CH, 19,5cm	HB2673-08			
Plester Saugrohr, 9CH, 19,5cm	HB2673-09			
Plester Saugrohr, 10CH, 19,5cm	HB2673-10			
Wiet Saugrohr, 18GA	HB2673-18			
Wiet Saugrohr, 20GA	HB2673-20			
Wiet Saugrohr, 22GA	HB2673-22			
Baron Saugrohr, 3CH, 13cm	HB2673-23			
Wiet Saugrohr, 24GA	HB2673-24			
Baron Saugrohr, 5CH, 13cm	HB2673-25			
Wiet Saugrohr, 26GA	HB2673-26			
Baron Saugrohr, 7CH, 13cm	HB2673-27			
Baron Saugrohr, 3CH, Arbeitslänge: 89mm	HB2673-33			
Baron Saugrohr, 5CH, Arbeitslänge: 89mm	HB2673-35			
Baron Saugrohr, 7CH, Arbeitslänge: 89mm	HB2673-37			
Baron Saugrohr, 9CH, Arbeitslänge: 89mm	HB2673-39			
Klima-Rosegger Punktionskanüle	HB2674			
Schuknecht Saugrohr, 20GA, Arbeitslänge 11,4cm	HB2674-01			
Schuknecht Saugrohr, 24GA, Arbeitslänge 11,4cm	HB2674-02			
Schmid Gefäßspülkanüle, Ø 3,0mm	HB2674-30			
Schmid Gefäßspülkanüle, Ø 4,0mm	HB2674-40			
Schmid Gefäßspülkanüle, Ø 5,0mm	HB2674-50			
Schmid Gefäßspülkanüle, Ø 6,0mm	HB2674-60			
Mock Gefäßspülkanüle, 6cm	HB2675-06			
Verres Kanüle, 2x80mm	HB2678-01			
Verres Kanüle, 2x100mm	HB2678-02			
Verres Kanüle, 2x120mm	HB2678-03			



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
Verres Kanüle, 2x150mm	HB2678-04			
Verres Kanüle, 2x170mm	HB2678-05			
Set: Iowa Instrument, 1,2x80mm inkl. Kanüle	HB2679-00			
Yankauer Saugrohr, 6mm, 30cm	HB2680			
Yankauer Saugrohr, Bohrung 1,5mm, Ø8mm, 21cm	HB2680-21			
Walton-Yankauer Saugrohr mit Hahn	HB2680-33			
Poole Saugrohr, 10mm, 22cm	HB2681			
Poole Saugrohr, gebogen, 8mm,	HB2682			
De Bakey Saugrohr, 27cm	HB2683			
ANDREWS-PYNCHON Saugrohr, 24cm	HB2683-24			
De Bakey Saugrohr, ø 5mm, 16cm	HB2684-01			
De Bakey Saugrohr, ø 5mm, 27cm	HB2684-02			
Finsterer Saug- und Spülkanüle	HB2685			
Cooley Saugrohr, Ø8mm, 33cm	HB2685-01			
Saugrohr, 90°, 21cm	HB2686-01			
Saugrohr, 60°, 27cm	HB2686-02			
Saugrohr, 45°, 28cm	HB2686-03			
Gruber Saugrohr, 14,5cm	HB2687-01			
Kahn-Frazier Saugrohr, biegsam,	HB2687-09			
Kahn-Frazier Saugrohr, biegsam,	HB2687-10			
Sinus Saugrohr Ø 2,5mm, Höhe 22,0mm	HB2687-21			
Sinus Saugrohr Ø 2,5mm, Höhe 14,0mm	HB2687-22			
Sinus Saugrohr Ø 3,0mm, Höhe 22,0mm	HB2687-31			
Sinus Saugrohr Ø 3,0mm, Höhe 14,0mm	HB2687-32			
Sinus Saugrohr Ø 4,0mm, Höhe 22,0mm	HB2687-41			
Sinus Saugrohr Ø 4,0mm, Höhe 14,0mm	HB2687-42			
House Saugrohr 12x14 FR, 90,0mm Arbeitslänge	HB2688-12			
House Saugrohr 2 x 2,5 FR, 90mm Arbeitslänge	HB2688-21			
House Saugrohr 2,5x4 FR, 70,0mm Arbeitslänge	HB2688-22			
House Saugrohr 2,5x4 FR, 90,0mm Arbeitslänge	HB2688-23			
House Saugrohr 4 x 5 FR, 70,0mm Arbeitslänge	HB2688-41			



Device name or Basic UDI-DI (under MDR appli- cation)		MDR Device classifi- cation (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification
House Saugrohr 4 x 5 FR, 90,0mm Arbeitslänge	HB2688-42			
House Saugrohr 5 x 7 FR, 90,0mm Arbeitslänge	HB2688-51			
House Saugrohr 5 x 7 FR, 70,0mm Arbeitslänge	HB2688-52			
House-Radpour Saug-Irrigator, 7Fr, Arbeitslänge 8,9cm	HB2688-55			
House Saugrohr 6 x 8 FR, 90,0mm Arbeitslänge	HB2688-61			
House Saugrohr 7 x 10 FR, 90,0mm Arbeitslänge	HB2688-71			
House-Radpour Saug-Irrigator, 10Fr, Arbeitslänge 8,9cm	HB2688-75			
House Saugrohr 8 x 12 FR, 90,0mm Arbeitslänge	HB2688-81			
Tonsillenkanüle, gerade	HB2700-20			
Tonsillenkanüle, abgewinkelt	HB2700-21			
Tonsillenkanüle, gebogen 90°	HB2700-22			
Tonsillenkanüle, gebogen 45°	HB2700-23			
Tonsillenkanüle, bajonettförmig	HB2700-24			
Kanüle für Kehlkopfspritze	HB2700-25			
Absaugrohr f. Laryngologie-In.	HB4272-00			
Saugkanüle, 250mm, Ø 2,0mm	HB4277-20			
Saugkanüle, 250mm, Ø 2,5mm	HB4277-25			
Saugkanüle, 250mm, Ø 3,0mm	HB4277-30			
Saugkanüle, 250mm, Ø 4,0mm	HB4277-40			
Aspiration needle, suction tube	HB4278-00			
Aspiration needle tip 23GA	HB4278-23			
Saugraspatorium, bajonettför- mig, 5mm, 20cm	HB5648-05			
Device 2 Basic UDI-DI: 04058368052L030199G2		☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☐ Class IIb / Class IIb implantable (ex- empted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Menghini Biopsiekanüle, 1x35mm	HB2676-01			
Menghini Biopsiekanüle, 1x70mm	HB2676-02			
Menghini Biopsiekanüle, 1,2x70	HB2676-03			
Menghini Biopsieka- nüle,1,2x100	HB2676-04			
Menghini Biopsiekanüle, 1,4x70	HB2676-05			
Menghini Biopsieka- nüle,1,4x100	HB2676-06			
Menghini Biopsiekanüle, 1,6x70	HB2676-07			



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
Menghini Biopsiekannüle, 1,8x100	HB2676-08			
Novak Biopsiekürette, Fig.1,	HB5060-01			
Novak Biopsiekürette, Fig.2,	HB5060-02			
Novak Biopsiekürette, Fig.3,	HB5060-03			
Novak Biopsiekürette, Fig.4,	HB5060-04			
Randall Biopsiekürette,	HB5060-05			
Novak-Schoeckaert Biopsiekür. HB5060-04 umarbeiten	HB5067			
Device 3 (EMD: Z12010902) Basic UDI-DI: 04058368250Z120109024D		☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Bipolare Schere, 18cm, geb.,	HF9680-18			
Bipolare Schere, 21cm, geb.,	HF9680-21			
Bipolare Schere, 23cm, geb.,	HF9680-23			
Bipolare Schere, 28cm, geb.,	HF9680-28			
Bipolare Schere, 18cm, geb., Fen	HF9685-18			
Bipolare Schere, 21cm, geb., Fen	HF9685-21			
Bipolare Schere, 23cm, geb., Fen	HF9685-23			
Bipolare Schere, 28cm, geb., Fen	HF9685-28			
Device 4 (EMD: Z12010902) Basic UDI-DI: 04058368251Z120109025A		☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Bipolarer Handgriff mit einem	HF9590-01			
Elektr-Handgriff, 2,4mm, 2 Tasn	HF9721-24			
Elektrodenhandgriff für 4mm Elektroden, mit 2 Tasten	HF9721-40			
Elektr-Handgriff, 2,4mm, 2 Tasn	HF9723-24			
Elektr-Handgriff, 4mm, 2 Tasten	HF9723-40			
Elektr-Handgriff, 2,4mm, 2 Tasn	HF9724-24			
Elektr-Handgriff, 4mm, 2 Tasten, Erbe Stecker	HF9724-40			
Einmal-Handgriff, 2,4mm El. Mindestabnahme 100/Pack	HF9725-24			
Elektrodenhandgriff 2,4mm	HF9726-24			
Elektrodenhandgriff 2,4mm	HF9727-24			
Elektrodenhandgriff 4mm	HF9727-40			
Argon-Handgriff 4mm, 2 Tasten	HF9729-40			
Elektrodenhandgriff 4mm	HF9730-40			
Elektrodenhandgriff 4mm	HF9731-40			



Device name or Basic UDI-DI (under MDR appli- cation)	MDR Device classi- fication (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification																																								
Device 5 (EMD: Z12010902) Basic UDI-DI: 04058368252Z1201090267 <table><tr><td>Fußschalter</td><td>HF9533</td></tr><tr><td>Einzel-Fußschalter für HBS100</td><td>HF9533-01</td></tr><tr><td>Einzel-Fußschalter, Kabel- länge 4,5m, für HBS300 (6-po- liger Anschl.)</td><td>HF9533-02</td></tr><tr><td>Doppel- Fußschalter</td><td>HF9535</td></tr><tr><td>Doppel-Fußschalter, mit Bügel</td><td>HF9535-01</td></tr><tr><td>Funk Doppel-Fußschalter</td><td>HF9537</td></tr><tr><td>Doppelfußschalter für HEBU</td><td>HF9537-02</td></tr><tr><td>Doppel-Fußschalter, ohne Bü- gel, mit 4-pin Stecker</td><td>HF9539</td></tr><tr><td>Doppel-Fußschalter, ohne Bü- gel</td><td>HF9539-01</td></tr><tr><td>Doppel-Fußschalter, ohne Bü- gel, ohne Stecker</td><td>HS9539-00</td></tr></table>	Fußschalter	HF9533	Einzel-Fußschalter für HBS100	HF9533-01	Einzel-Fußschalter, Kabel- länge 4,5m, für HBS300 (6-po- liger Anschl.)	HF9533-02	Doppel- Fußschalter	HF9535	Doppel-Fußschalter, mit Bügel	HF9535-01	Funk Doppel-Fußschalter	HF9537	Doppelfußschalter für HEBU	HF9537-02	Doppel-Fußschalter, ohne Bü- gel, mit 4-pin Stecker	HF9539	Doppel-Fußschalter, ohne Bü- gel	HF9539-01	Doppel-Fußschalter, ohne Bü- gel, ohne Stecker	HS9539-00	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows Certificate G1 049044 0016 Rev. 00 NB 0123																				
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Doppel- Fußschalter	HF9535																																										
Doppel-Fußschalter, mit Bügel	HF9535-01																																										
Funk Doppel-Fußschalter	HF9537																																										
Doppelfußschalter für HEBU	HF9537-02																																										
Doppel-Fußschalter, ohne Bü- gel, mit 4-pin Stecker	HF9539																																										
Doppel-Fußschalter, ohne Bü- gel	HF9539-01																																										
Doppel-Fußschalter, ohne Bü- gel, ohne Stecker	HS9539-00																																										
Device 6 (EMD: Z12010902) Basic UDI-DI: 04058368253Z1201090274 <table><tr><td>Bip.-Pinz.ausw.Spitze,ger.,110</td><td>HF9600-11</td></tr><tr><td>Bip.-Pinz.ausw.Spitze,ger.,160</td><td>HF9600-16</td></tr><tr><td>Bip.-Pinz.ausw.Spitze,ger.,195</td><td>HF9600-19</td></tr><tr><td>Bip.-Pinz.ausw.Spitze,ger.,220</td><td>HF9600-22</td></tr><tr><td>Spitzen f. Bi-Pinz- ger.</td><td>HF9601-01</td></tr><tr><td>Spitzen f. Bi-Pinz- geb.</td><td>HF9601-02</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 0,5m</td><td>HF9602-01</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 0,5m</td><td>HF9602-02</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 1,0m</td><td>HF9603-01</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 1,0m</td><td>HF9603-02</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 2,0m</td><td>HF9604-01</td></tr><tr><td>Spitzen für Bi-Pinz. ger. 2,0m</td><td>HF9604-02</td></tr><tr><td>Bipolar-Pinz., ger.,Nadel,110m</td><td>HF9611-11</td></tr><tr><td>Bipolar-Pinz., ger.,Nadel,160m</td><td>HF9611-16</td></tr><tr><td>Bipolar-Pinz., ger.,0,5mm,110m</td><td>HF9612-11</td></tr><tr><td>Bipolar-Pinzette, isoliert, ge- rade, 0,5mm, 110mm, Non- Stick</td><td>HF9612-11N</td></tr><tr><td>Bipolar-Pinz., ger.,0,5mm,110m</td><td>HF9612-11NUS</td></tr><tr><td>Bipolar-Pinz., ger.,0,5mm,160mm</td><td>HF9612-16</td></tr><tr><td>Bipolar-Pinz., ger.,0,5mm,160m</td><td>HF9612-16N</td></tr><tr><td>Bipolar-Pinz., ger.,0,5mm,160m</td><td>HF9612-16NUS</td></tr></table>	Bip.-Pinz.ausw.Spitze,ger.,110	HF9600-11	Bip.-Pinz.ausw.Spitze,ger.,160	HF9600-16	Bip.-Pinz.ausw.Spitze,ger.,195	HF9600-19	Bip.-Pinz.ausw.Spitze,ger.,220	HF9600-22	Spitzen f. Bi-Pinz- ger.	HF9601-01	Spitzen f. Bi-Pinz- geb.	HF9601-02	Spitzen für Bi-Pinz. ger. 0,5m	HF9602-01	Spitzen für Bi-Pinz. ger. 0,5m	HF9602-02	Spitzen für Bi-Pinz. ger. 1,0m	HF9603-01	Spitzen für Bi-Pinz. ger. 1,0m	HF9603-02	Spitzen für Bi-Pinz. ger. 2,0m	HF9604-01	Spitzen für Bi-Pinz. ger. 2,0m	HF9604-02	Bipolar-Pinz., ger.,Nadel,110m	HF9611-11	Bipolar-Pinz., ger.,Nadel,160m	HF9611-16	Bipolar-Pinz., ger.,0,5mm,110m	HF9612-11	Bipolar-Pinzette, isoliert, ge- rade, 0,5mm, 110mm, Non- Stick	HF9612-11N	Bipolar-Pinz., ger.,0,5mm,110m	HF9612-11NUS	Bipolar-Pinz., ger.,0,5mm,160mm	HF9612-16	Bipolar-Pinz., ger.,0,5mm,160m	HF9612-16N	Bipolar-Pinz., ger.,0,5mm,160m	HF9612-16NUS	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Bip.-Pinz.ausw.Spitze,ger.,110	HF9600-11																																										
Bip.-Pinz.ausw.Spitze,ger.,160	HF9600-16																																										
Bip.-Pinz.ausw.Spitze,ger.,195	HF9600-19																																										
Bip.-Pinz.ausw.Spitze,ger.,220	HF9600-22																																										
Spitzen f. Bi-Pinz- ger.	HF9601-01																																										
Spitzen f. Bi-Pinz- geb.	HF9601-02																																										
Spitzen für Bi-Pinz. ger. 0,5m	HF9602-01																																										
Spitzen für Bi-Pinz. ger. 0,5m	HF9602-02																																										
Spitzen für Bi-Pinz. ger. 1,0m	HF9603-01																																										
Spitzen für Bi-Pinz. ger. 1,0m	HF9603-02																																										
Spitzen für Bi-Pinz. ger. 2,0m	HF9604-01																																										
Spitzen für Bi-Pinz. ger. 2,0m	HF9604-02																																										
Bipolar-Pinz., ger.,Nadel,110m	HF9611-11																																										
Bipolar-Pinz., ger.,Nadel,160m	HF9611-16																																										
Bipolar-Pinz., ger.,0,5mm,110m	HF9612-11																																										
Bipolar-Pinzette, isoliert, ge- rade, 0,5mm, 110mm, Non- Stick	HF9612-11N																																										
Bipolar-Pinz., ger.,0,5mm,110m	HF9612-11NUS																																										
Bipolar-Pinz., ger.,0,5mm,160mm	HF9612-16																																										
Bipolar-Pinz., ger.,0,5mm,160m	HF9612-16N																																										
Bipolar-Pinz., ger.,0,5mm,160m	HF9612-16NUS																																										



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
Bipolar-Pinz., ger., 0,5mm, 190m	HF9612-19N			
Bipolar-Pinz., ger., 0,5mm, 190m	HF9612-19NUS			
Bipolar-Pinz., ger., 0,5mm, 220mm, Non-Stick	HF9612-22N			
Bipolar-Pinz., ger., 1,0mm, 110m	HF9613-11			
Adson bipolare Pinzette, 1,0mm, 12cm	HF9613-12			
Adson bipolare Pinzette, 1,0mm, 12cm, Non-Stick	HF9613-12N			
Bipolar-Pinz., ger., 1,0mm, 160m	HF9613-16			
Bipolar-Pinz., ger., 1,0mm, 160m	HF9613-16N			
Bipolar-Pinz., ger., 1,0mm, 160m	HF9613-16NUS			
Bipolar-Pinz., ger., 1,0mm, 195m	HF9613-19			
Bipolar-Pinz., ger., 1,0mm, 190m	HF9613-19N			
Bipolar-Pinz., ger., 1,0mm, 190m	HF9613-19NUS			
Bipolar-Pinz., ger., 1,0mm, 220m	HF9613-22			
Bipolar-Pinz., ger., 1,0mm, 220mm, Non-Stick	HF9613-22N			
Bipolar-Pinz., ger., 1,0mm, 220mm, Non-Stick	HF9613-22NUS			
Bipolar-Pinz., ger., 2,0mm, 160m	HF9614-16			
Bipolar-Pinz., ger., 2,0mm, 160m	HF9614-16N			
Bipolar-Pinz., ger., 2,0mm, 160m	HF9614-16NUS			
Bipolar-Pinz., ger., 2,0mm, 195m	HF9614-19			
Bipolar-Pinz., ger., 2,0mm, 190m	HF9614-19N			
Bipolar-Pinzette, isoliert, gerade, 2,0mm, 190mm, Non-Stick	HF9614-19NUS			
Bipolar-Pinz., ger., 2,0mm, 220m	HF9614-22			
Bipolar-Pinzette, isoliert, gerade, 2,0mm, 220mm, Non-Stick	HF9614-22N			
Bipolar-Pinzette, isoliert, gerade, 2,0mm, 220mm, Non-Stick	HF9614-22NUS			
Adson bipolare Pinzette, 1,5mm, 12cm	HF9615-12			
Adson bipolare Pinzette, 1,5mm, 12cm, Non-Stick	HF9615-12N			
Adson bipolare Pinzette, 1,2mm, 12cm	HF9616-12			



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
Adson bipolare Pinzette, 1,2mm, 12cm, Non-Stick	HF9616-12N			
Bipolar-Pinz., ger., 3,0mm, 220m	HF9617-22			
Bipolar-Pinz., geb., Nadel, 110m	HF9621-11			
Bipolar-Pinz., geb., Nadel, 160m	HF9621-16			
Bipolare Pinzette, gebogen, Nadel, 190mm	HF9621-19			
Bipolar-Pinz., geb., 0,5mm, 110m	HF9622-11			
Bipolar-Pinz., geb., 0,5mm, 160m	HF9622-16			
Bipolar-Pinz., geb., 0,5mm, 160m	HF9622-16N			
Bipolar-Pinz., geb., 0,5mm, 160m	HF9622-16NUS			
Bipolar-Pinz., geb., 0,5mm, 195m	HF9622-19N			
Bipolar-Pinz., geb., 0,5mm, 195m	HF9622-19NUS			
Bipolare Pinzette, isoliert, 0,5mm, 22cm, Non-Stick	HF9622-22N			
Bipolar-Pinz., geb., 1,0mm, 110m	HF9623-11			
Bipolar-Pinz., geb., 1,0mm, 160m	HF9623-16			
Bipolar-Pinz., geb., 1,0mm, 160m	HF9623-16N			
Bipolar-Pinz., geb., 1,0mm, 160m	HF9623-16NUS			
Bipolar-Pinz., geb., 1,0mm, 195m	HF9623-19			
Bipolar-Pinz., geb., 1,0mm, 195m	HF9623-19N			
Bipolar-Pinz., geb., 1,0mm, 195m	HF9623-19NUS			
Bipolar-Pinz., geb., 1,0mm, 220mm	HF9623-22			
Bipolare Pinzette, isoliert, 1,0mm, 22cm, Non-Stick	HF9623-22N			
Bipolar-Pinz., geb., 2,0mm, 160m	HF9624-16			
Bipolar-Pinz., geb., 2,0mm, 160m	HF9624-16N			
Bipolar-Pinz., geb., 2,0mm, 160m	HF9624-16NUS			
Bipolar-Pinz., geb., 2,0mm, 195m	HF9624-19			
Bipolar-Pinz., geb., 2,0mm, 195m	HF9624-19N			
Bipolar-Pinz., geb., 2,0mm, 195m	HF9624-19NUS			
Bipolar-Pinz., geb., 2,0mm, 220m	HF9624-22			



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
Bipolare Pinzette, isoliert, 2,0mm, 22cm, Non-Stick	HF9624-22N			
Bip.-Baj.Pinze.,ausw.Sp., 160mm	HF9630-16			
Bip.-Baj.Pinze.,ausw.Sp., 195mm	HF9630-19			
Bip.-Baj.Pinze.,ausw.Sp., 220mm	HF9630-22			
Bipolar-Baj-Pinze.,ger,Nad,165m	HF9631-16			
Bip. Baj.-Pinzette, ger., Nadel, 195mm	HF9631-19			
Bip.-Baj-Pinze.,ger.,0,5mm,165mm	HF9632-16			
Bip.-Baj-Pinze.,ger.,0,5mm,165mm	HF9632-16N			
Bip.-Baj-Pinze.,ger.,0,5mm,165mm	HF9632-16NUS			
Bip.-Baj-Pinze.,ger.,0,5mm,195m	HF9632-19			
Bip.-Baj-Pinze.,ger.,0,5mm,190mm	HF9632-19N			
Bip.-Baj-Pinze.,ger.,0,5mm,195m	HF9632-19NUS			
Bip.-Baj-Pinze.,ger.,0,5mm,220mm	HF9632-22N			
Bip.-Baj-Pinze.,ger.,0,5mm,240mm	HF9632-24N			
Bip.-Baj-Pinze.,ger.,0,5mm,260mm	HF9632-26N			
Bip.-Baj-Pinze.,ger.,1,0mm,165m	HF9633-16			
Bip.-Baj-Pinze.,ger.,1,0mm,165mm	HF9633-16N			
Bip.-Baj-Pinze.,ger.,1,0mm,195m	HF9633-19			
Bip.-Baj-Pinze.,ger.,1,0mm,195m	HF9633-19N			
Bip.-Baj-Pinze.,ger.,1,0mm,195m	HF9633-19NUS			
Bip.-Baj-Pinze.,ger.,1,0mm,220mm	HF9633-22			
Bip.-Baj-Pinze.,ger.,1,0mm,220mm	HF9633-22N			
Bip.-Baj-Pinze.,ger.,1,0mm,220m	HF9633-22NUS			
Bip.-Baj-Pinze.,ger.,1,0mm,240mm	HF9633-24			
Bip.-Baj-Pinze.,ger.,1,0mm,240mm	HF9633-24N			
Bip.-Baj-Pinze.,ger.,1,0mm,260mm	HF9633-26			
Bip.-Baj-Pinze.,ger.,1,0mm,260mm	HF9633-26N			
Bip.-Baj-Pinze.,ger.,2,0mm,19m	HF9634-19			



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
Bip.-Baj-Pinz., ger., 2,0mm, 19m	HF9634-19N			
Bip.-Baj-Pinz., ger., 2,0mm, 19m	HF9634-19NUS			
Bip.-Baj-Pinz., ger., 2,0mm, 220mm	HF9634-22			
Bip.-Baj-Pinz., ger., 2,0mm, 220mm	HF9634-22N			
Bip.-Baj-Pinz., ger., 2,0mm, 240mm	HF9634-24			
Bip.-Baj-Pinz., ger., 2,0mm, 240mm	HF9634-24N			
Bip.-Baj-Pinz., ger., 2,0mm, 260mm	HF9634-26			
Bip.-Baj-Pinz., ger., 2,0mm, 260mm	HF9634-26N			
Bip.-Baj-Pinz., ger., 1,5mm, 195mm	HF9635-19			
Bip.-Baj-Pinz., ger., 1,5mm, 195mm	HF9635-19N			
Bip.-Baj-Pinz., ger., 1,5mm, 220mm	HF9635-22			
Bip.-Baj-Pinz., ger., 1,5mm, 220mm	HF9635-22N			
Bip.-Baj-Pinz., ger., 1,5mm, 240mm	HF9635-24			
Bip.-Baj-Pinz., ger., 1,5mm, 240mm	HF9635-24N			
Bip.-Baj-Pinz., ger., 1,5mm, 260mm	HF9635-26			
Bip.-Baj-Pinz., ger., 1,5mm, 260mm	HF9635-26N			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 195mm	HF9636-19			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 195mm, Non-Stick	HF9636-19N			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 220mm	HF9636-22			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 220mm, Non-Stick	HF9636-22N			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 240mm	HF9636-24			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 240mm, Non-Stick	HF9636-24N			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 260mm	HF9636-26			
Bipolar-Bajonettpinzette, isoliert, 0,7mm, 260mm, Non-Stick	HF9636-26N			
Bip.-Baj-Pinz., aufwärts geb.	HF9643-19			
Bipolare Pinzette, isoliert	HF9643-19N			
Bipolare Pinzette, isoliert	HF9643-19NUS			
Bip.-Baj-Pinz., aufwärts geb.	HF9643-22			



Device name or Basic UDI-DI (under MDR appli- cation)		MDR Device classifi- cation (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification																																																						
<table><tr><td>Bip.-Baj-Pinz.,abwärts geb.</td><td>HF9653-19</td></tr><tr><td>Bip.-Baj-Pinz.,abwärts geb.</td><td>HF9653-19N</td></tr><tr><td>Bip.-Baj-Pinz.,abwärts geb.</td><td>HF9653-19NUS</td></tr><tr><td>Bipolar-Bajonettpinzette</td><td>HF9662-22</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9662-22N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9662-24N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9662-26N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9663-24N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9663-26N</td></tr><tr><td>Bipolar-Saugpinzette, 19cm</td><td>HF9664-19</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9664-24N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9664-26N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9665-24N</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9665-26N</td></tr><tr><td>Bipolar-Bajonettpinzette</td><td>HF9672-22</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9672-22N</td></tr><tr><td>Bipolar-Bajonettpinzette</td><td>HF9682-22</td></tr><tr><td>Bipolare Pinzette, isoliert</td><td>HF9682-22N</td></tr><tr><td>Bipolar-Pinz.,geb,1,0mm, 170mm</td><td>HF9693-17</td></tr><tr><td>Bipolar-Pinz.,1,0mm, 190m</td><td>HF9693-19</td></tr><tr><td>Monoplaire Pinzette, 18cm</td><td>HF9960-18</td></tr><tr><td>Monoplaire Pinzette, 20cm</td><td>HF9960-20</td></tr><tr><td>Monoplaire Pinzette, 25cm</td><td>HF9960-25</td></tr><tr><td>Monoplaire Pinzette An- sch.,18cm</td><td>HF9961-18</td></tr><tr><td>Monoplaire Pinzette An- sch.,20cm</td><td>HF9961-20</td></tr><tr><td>Monoplaire Pinzette An- sch.,25cm</td><td>HF9961-25</td></tr><tr><td>Monopolare Grünwald-Jansen</td><td>HF9963-23</td></tr></table>		Bip.-Baj-Pinz.,abwärts geb.	HF9653-19	Bip.-Baj-Pinz.,abwärts geb.	HF9653-19N	Bip.-Baj-Pinz.,abwärts geb.	HF9653-19NUS	Bipolar-Bajonettpinzette	HF9662-22	Bipolare Pinzette, isoliert	HF9662-22N	Bipolare Pinzette, isoliert	HF9662-24N	Bipolare Pinzette, isoliert	HF9662-26N	Bipolare Pinzette, isoliert	HF9663-24N	Bipolare Pinzette, isoliert	HF9663-26N	Bipolar-Saugpinzette, 19cm	HF9664-19	Bipolare Pinzette, isoliert	HF9664-24N	Bipolare Pinzette, isoliert	HF9664-26N	Bipolare Pinzette, isoliert	HF9665-24N	Bipolare Pinzette, isoliert	HF9665-26N	Bipolar-Bajonettpinzette	HF9672-22	Bipolare Pinzette, isoliert	HF9672-22N	Bipolar-Bajonettpinzette	HF9682-22	Bipolare Pinzette, isoliert	HF9682-22N	Bipolar-Pinz.,geb,1,0mm, 170mm	HF9693-17	Bipolar-Pinz.,1,0mm, 190m	HF9693-19	Monoplaire Pinzette, 18cm	HF9960-18	Monoplaire Pinzette, 20cm	HF9960-20	Monoplaire Pinzette, 25cm	HF9960-25	Monoplaire Pinzette An- sch.,18cm	HF9961-18	Monoplaire Pinzette An- sch.,20cm	HF9961-20	Monoplaire Pinzette An- sch.,25cm	HF9961-25	Monopolare Grünwald-Jansen	HF9963-23			
Bip.-Baj-Pinz.,abwärts geb.	HF9653-19																																																									
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Monopolare Grünwald-Jansen	HF9963-23																																																									
Device 7 (EMD: Z12010902) Basic UDI-DI: 04058368254Z120109027Z <table><tr><td>Bipolare Elektroden</td><td>HF9580-01</td></tr><tr><td>Bipolare Elektroden</td><td>HF9580-02</td></tr><tr><td>Bipolare Elektroden</td><td>HF9580-03</td></tr><tr><td>Bipolare Elektroden</td><td>HF9580-04</td></tr><tr><td>Bipolare Elektroden</td><td>HF9580-05</td></tr><tr><td>Bip. Fasszange, Schneider</td><td>HF9580-06</td></tr><tr><td>Bull Mikrozange zum bipolaren Koagulieren und Schneiden</td><td>HF9580-07</td></tr><tr><td>Schaftrohr f Koagulations- zange</td><td>HF9580-34</td></tr><tr><td>Ersatzklingen</td><td>HF9581-01</td></tr><tr><td>Gefäßversiegelungsinstrument</td><td>HF9581-20</td></tr></table>		Bipolare Elektroden	HF9580-01	Bipolare Elektroden	HF9580-02	Bipolare Elektroden	HF9580-03	Bipolare Elektroden	HF9580-04	Bipolare Elektroden	HF9580-05	Bip. Fasszange, Schneider	HF9580-06	Bull Mikrozange zum bipolaren Koagulieren und Schneiden	HF9580-07	Schaftrohr f Koagulations- zange	HF9580-34	Ersatzklingen	HF9581-01	Gefäßversiegelungsinstrument	HF9581-20	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123																																		
Bipolare Elektroden	HF9580-01																																																									
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Device name or Basic UDI-DI (under MDR appli- cation)		MDR Device classi- fication (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification
Gefäßversiegelungsinstrument	HF9581-37			
BiSeal Gefäßversiegelungs- instruments, 5mm, Griff einzeln, mit Kabel	HF9582-00			
Aussenschaft für BiSeal, 25cm	HF9582-25			
Schubstange für BiSeal Ge- fäßversiegelungsinstrument, 25cm	HF9582-27			
Klingenhalterrohr für BiSeal Gefäßversiegelungsinstru- ment, 25cm	HF9582-28			
Aussenschaft für BiSeal, 34cm	HF9582-34			
Schubstange für BiSeal Ge- fäßversiegelungsinstrument, 34cm	HF9582-36			
Klingenhalterrohr für BiSeal Gefäßversiegelungsinstru- ment, 34cm	HF9582-37			
Arbeitselement bipolar, passiv	HF9585-01			
Arbeitselement bipolar, aktiv	HF9585-02			
Opturator	HF9585-14			
Zystoskop 4mm, l=302, 30°/70°, autoklavierbar	HF9586-01			
Zystoskop 4mm, l=302, 0°, au- toklavierbar	HF9586-02			
Zystoskop 4mm, l=302, 12°/60°, autoklavierbar	HF9586-03			
Bipolare Klemme, BiSeal,	HF9691-14			
Bipolare Klemme, BiSeal,	HF9691-16			
Bipolare Klemme, BiSeal,	HF9691-18			
Bipolare Klemme, BiSeal,	HF9691-23			
Bipolare Klemme, BiSeal,	HF9691-28			
Bipolare Klemme, BiSeal,	HF9692-14			
Bipolare Klemme, BiSeal,	HF9692-21			
Monopolare Klemmen	HF9965-14			
Monopolare Klemmen	HF9965-19			
Device 8 (EMD: Z12010902) Basic UDI-DI: 04058368255Z120109028W		☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Elektrode mit Schneidfunktion für BiSeal Gefäßversiegelungsinstru- ment	HF9582-26			
Elektrode mit Schneidfunktion für BiSeal Gefäßversiegelungsinstru- ment	HF9582-35			
Bipolare Elektrode, Schlinge, 90°, gewinkelt, 5 Stück pro Pack	HF9584-01			
Bipolare Elektrode, Schlinge, 60°, gewinkelt, 5 Stück pro Pack	HF9584-02			
Bipolare Elektrode, Kugel, 5 Stück pro Pack	HF9584-03			



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
Bipolare Elektrode, Schlinge, 0°, gerade, 5 Stück pro Pack	HF9584-04	☐ Class III implantable custom-made-device		
Bipolare Elektrode, Messer, 5 Stück pro Pack	HF9584-05			
Bipolare Elektrode, Walze, 5 Stück pro Pack	HF9584-06			
Bipolar Varex II Elektroden,	HF9591-03			
Bipolar Varex II Elektroden,	HF9591-04			
Bipolar Varex II Elektroden,	HF9591-06			
Bipolar Elektr. Meuser 90°	HF9695-01			
Bipolar Elektr. Meuser 45°	HF9695-02			
Bipolar Elektr. Binner	HF9695-03			
Bipolar Elektr. Meuser	HF9695-04			
Bipolare Koagulationselektrode	HF9695-05			
Bipolar Elektr. Meuser	HF9695-06			
Bipolar Elektr. Binner	HF9695-07			
Bipolare Koagulationselektrode	HF9695-09			
Bipolare Koagulationselektrode	HF9695-10			
Bipolare Koagulationselektrode	HF9695-11			
Bipolare Koagulationselektrode	HF9696-01			
Bipolare Koagulationselektrode	HF9696-02			
Bipolare Koagulationselektrode	HF9696-03			
Bipolare Koagulationselektrode	HF9696-04			
Bipolare Koagulationselektrode	HF9696-05			
Bipolare Nadel und Haken Slime	HF9697-01			
Bipolare Nadel und Haken Slime	HF9697-02			
Bipolare Nadel und Haken Slime	HF9697-03			
Bipol. Arthroskopie Elektrode,	HF9698-01			
Bipol. Arthroskopie Elektrode,	HF9698-02			
Bipol. Arthroskopie Elektrode,	HF9698-03			
Bipolare Vaporisationselektrode, VAP, 90°, 170mm	HF9698-06			
Bipol. Arthroskopie Elektrode,	HF9699-02			
Bipol. Arthroskopie Elektrode,	HF9699-03			
Mono.Elekt.Ø1,6mm, Fig.1, starr	HF9801-01			
Mono.Elekt.Ø1,6mm, Fig.11, starr	HF9801-11			
Mono.Elekt.Ø1,6mm, Fig.12, starr	HF9801-12			
Mono.Elekt.Ø1,6mm, Fig.13, starr	HF9801-13			
Mono.Elekt.Ø1,6mm, Fig.33, starr	HF9801-33			
Mono.Elekt.Ø1,6mm, Fig.34, starr	HF9801-34			
Mono.Elekt.Ø1,6mm, Fig.35, starr	HF9801-35			
Koagulationsnadelelektrode, Ø1,5mm, Fig. 36, starr, 5 Stück	HF9801-36			
Monopol. Kugelelektrode, Ø1,7mm, gerade, Fig. 37, starr, 5 Stück	HF9801-37			
Monopol. Kugelelektrode, Ø3mm, gerade, Fig. 38, starr, 5 Stück	HF9801-38			



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
Mono.Elekt.ø2,4mm,Messer25x20	HF9805-24			
Mono.Elekt.ø2,4mm,fein,	HF9805-52			
Mono.Elekt.ø2,4mm,Spatel2,5x20	HF9806-24			
Mono.Elekt.ø2,4mm,fein,	HF9806-52			
Mono.Elekt.ø2,4mm,Drahtschl.ø5	HF9807-24			
Mono.Elekt.ø2,4mm,fein,	HF9807-52			
Mono.Elekt.ø2,4mm,Drahtschl.ø0	HF9808-24			
Mono.Elekt.ø2,4mm,fein,	HF9808-52			
Mono.Elekt.ø2,4mm,Bandschl.ø10	HF9809-24			
Mono.Elekt.ø2,4mm,fein,	HF9809-52			
Mono.Elekt.ø2,4mm,Bandschl.ø15	HF9810-24			
Mono.Elekt.ø2,4mm,fein,	HF9810-52			
Mono.Elekt.ø2,4mm,Kugel ø 2mm	HF9811-24			
Mono.Elekt.ø2,4mm,fein,	HF9811-52			
Mono.Elekt.ø2,4mm,Kugel ø 4mm	HF9812-24			
Mono.Elekt.ø2,4mm,fein,	HF9812-52			
Mono.Elekt.ø2,4mm,Kugel ø 6mm	HF9813-24			
Mono.Elekt.ø2,4mm,fein,	HF9813-52			
Mono.Elekt.ø2,4mm,Nadel ø 0,5m	HF9814-24			
Mono.Elekt.ø2,4mm,Mikrodissektions-Nadel,kurz	HF9814-52			
Monopolare Elektrode ø4mm, Mikrodissektions-Nadel, kurz,	HF9814-54			
Mono.Elekt.ø2,4mm,Nadel ø 0,7m	HF9815-24			
Mono.Elekt.ø2,4mm,Messer25x20	HF9816-24			
Mono.Elekt.ø2,4mm,Spatel2,5x20	HF9817-24			
Mono.Elekt.ø2,4mm,Nadel ø0,5x2	HF9818-24			
Mono.Elekt.ø2,4mm,Nadel ø0,7	HF9819-24			
Mono.Elekt.ø2,4mm,Kugel ø 4mm	HF9820-24			
Mono.Elekt.ø 2,4mm, Schlinge	HF9821-21			
Mono.Elekt.ø2,4mm, Schlinge	HF9821-22			
Mono.Elekt.ø2,4mm, Schlinge	HF9821-23			
Mono.Elekt.ø2,4mm,Kugel ø 6mm	HF9821-24			
Mono.Elekt.ø2,4mm, Schlinge	HF9822-24			
Mono.Elekt.ø2,4mm, Schlinge	HF9823-24			
Mono.Elekt.ø2,4mm,Schaft,20x20	HF9824-24			
Mono.Elekt.ø2,4mm,Schaft,20x26	HF9825-24			
Microdissektions-Nadelelektrode	HF9825-61			
Microdissektions-Nadelelektrode	HF9825-62			
Microdissektions-Nadelelektrode	HF9825-63			
Microdissektions-Nadelelektrode	HF9825-64			
Microdissektions-Nadelelektrode	HF9825-65			
Microdissektions-Nadelelektrode	HF9825-66			
Microdissektions-Nadelelektrode	HF9825-67			
Microdissektions-Nadelelektrode	HF9825-68			
Nadelelektrode mit Keramikison	HF9825-80			



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
Nadelelektrode mit Keramikison	HF9825-81			
Nadelelektrode mit Keramikison	HF9825-82			
Nadelelektrode mit Keramikison	HF9825-83			
Nadelelektrode mit Keramikison	HF9825-84			
Nadelelektrode mit Keramikison	HF9825-85			
Nadelelektrode mit Keramikison	HF9825-86			
Nadelelektrode mit Keramikison	HF9825-87			
Mono.Elekt.ø2,4mm,Schaft,ø 10m	HF9826-24			
Mono.Elekt.ø2,4mm,Schaft,ø 15m	HF9827-24			
Mono.Elekt.ø2,4mm,Schaft,ø 20m	HF9828-24			
Mono.Elekt.ø2,4mm,Schaft,ø 25m	HF9829-24			
Monopolare Elektroden ø 2,4mm	HF9839-01			
Monopolare Elektroden ø 2,4mm	HF9839-02			
Monopolare Elektroden ø 2,4mm	HF9839-03			
Monopolare Elektroden ø 2,4mm	HF9839-04			
Monopolare Elektroden ø 2,4mm	HF9839-05			
Monopolare Elektroden ø 2,4mm	HF9839-06			
Monopolare Elektroden ø 2,4mm	HF9839-07			
Monopolare Elektroden ø 2,4mm	HF9839-08			
Mono.Elekt.ø4mm,Messer 25x3	HF9845-40			
Mono.Elekt.ø4mm,Messer 25x3,3	HF9846-40			
Mono.Elekt.ø4mm,Spatel 25x3,0	HF9847-40			
Mono.Elekt.ø4mm,Messer 25x3,3	HF9848-40			
Mono.Elekt.ø4mm,Messer, 20x1,0	HF9849-40			
Mono.Elekt.ø4mm,Messer 19x1,0	HF9850-40			
Mono.Elekt.ø4mm,Schneide 20x18	HF9851-40			
Mono.Elekt.ø4mm,Schneide 19x18	HF9852-40			
Mono.Elekt.ø4mm,Schneide25x2,2	HF9853-40			
Mono.Elekt.ø4mm,Drahtschl.ø 5m	HF9854-40			
Mono.Elekt.ø4mm,Drahtsch.ø 10m	HF9855-40			
Mono.Elekt.ø4mm,Bandschl.ø 10m	HF9856-40			
Mono.Elekt.ø4mm, Bandschlinge	HF9857-40			
Mono.Elekt.ø4mm,Kugel ø 2mm	HF9858-40			
Mono.Elekt.ø4mm,Kugel ° 2mm	HF9858-41			
Mono.Elekt.ø4mm,Kugel ø 4mm	HF9859-40			
Mono.Elekt.ø4mm,Kugel ° 4mm	HF9859-41			
Mono.Elekt.ø4mm,Kugel ø 6mm	HF9860-40			
Mono.Elekt.ø4mm,Nadel, ø 0,5mm	HF9861-40			
Mono.Elekt.ø4mm,Nadel, ø 0,7mm	HF9862-40			
Mono.Elekt.ø4mm,Nadel, ø 0,5mm	HF9863-40			
Mono.Elekt.ø4mm,Nadel, ø 0,7mm	HF9864-40			
Mono.Elekt.ø4mm,Spatel 16x2mm	HF9865-40			
Mono.Elekt.ø4mm,Schaft,2,0x16	HF9867-40			
Mono.Elekt.ø4mm,Schaft,2,4x10	HF9868-40			



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
Mono.Elekt.ø4mm,Schaft,2,4x10	HF9869-40			
Mono.Elekt.ø4mm,Schaft,2,5x20	HF9870-40			
Mono.Elekt.ø4mm,Schaft,3,3x25	HF9871-40			
Mono.Elekt.ø4mm,Schaft,2,5x20	HF9872-40			
Mono.Elekt.ø4mm,Schaft,ger.202	HF9873-40			
Mono.Elekt.ø4mm,Schaft,20x1,8	HF9874-40			
Mono.Elekt.ø4mm,Schaft,ø0,5x12	HF9875-40			
Mono.Elekt.ø4mm,Schaft,ø0,8x12	HF9876-40			
Mono.Elekt.ø4mm,Schaft,Dr. ø5	HF9877-40			
Mono.Elekt.ø4mm,Schaft,Dr. ø10	HF9878-40			
Monopolare Elektrode mit isoliertem Schaft, ø4mm, Kugel	HF9879-39			
Mono.Elekt.ø4mm,Schaft,ø 4mm,	HF9879-40			
Mono.Elekt.ø4mm, Schaft, ø4mm,	HF9879-41			
Mono.Elekt.ø4mm,Schaft,ø 6mm,	HF9880-40			
Mono.Elekt.ø4mm,Schaft,10x10	HF9881-40			
Mono.Elekt.ø4mm,Schaft,15x15	HF9882-40			
Mono.Elekt.ø4mm,Schaft,20x20	HF9883-40			
Mono.Elekt.ø4mm,Schaft,20x25	HF9884-40			
Mono.Elekt.ø4mm,Schaft,ø 10mm,	HF9885-40			
Mono.Elekt.ø4mm,Schaft,ø 15mm,	HF9886-40			
Mono.Elekt.ø4mm,Schaft,ø 20mm,	HF9887-40			
Mono.Elekt.ø4mm,Schaft,ø 25mm,	HF9888-40			
Mono.Elekt.ø4mm,m.isol.Schaft	HF9889-41			
Mono.Elekt.ø4mm,m.isol.Schaft	HF9889-42			
Mono.Elekt.ø4mm,m.isol.Schaft	HF9889-43			
Mono.Elekt.ø4mm,Schaft,ø 0,8m,	HF9890-40			
Mono.Elekt.ø4mm,Schaft,ø 0,5m,	HF9891-40			
Mono.Elekt.ø4mm,Schaft,ø 0,5m,	HF9892-40			
Mono.Elekt.ø4mm,Schaft,ø 2,0m,	HF9894-40			
Mono.Elekt.Arthr.ø4,1,5xø 0,6m	HF9895-40			
Mono.Elekt.Arthr.ø4,4xø 0,6mm	HF9896-40			
Mono.Elekt.Arthr.ø4,3xø 0,4mm	HF9897-40			
Mono.Elekt.Arthr.ø4,3xø 1,5mm	HF9898-40			
Microdissektions-Nadelelektrode	HF9899-01			
Microdissektions-Nadelelektrode	HF9899-02			
Microdissektions-Nadelelektrode	HF9899-03			
Microdissektions-Nadelelektrode	HF9899-04			
Microdissektions-Nadelelektrode	HF9899-05			
Microdissektions-Nadelelektrode	HF9899-06			
Microdissektions-Nadelelektrode	HF9899-07			
Microdissektions-Nadelelektrode	HF9899-08			
Nadelelektrode mit Keramikison	HF9899-20			
Nadelelektrode mit Keramikison	HF9899-21			
Nadelelektrode mit Keramikison	HF9899-22			



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
Nadelelektrode mit Keramikison	HF9899-23			
Nadelelektrode mit Keramikison	HF9899-24			
Nadelelektrode mit Keramikison	HF9899-25			
Nadelelektrode mit Keramikison	HF9899-26			
Nadelelektrode mit Keramikison	HF9899-27			
Mono.Elekt.Arthr.ø4,Kugel	HF9899-40			
Monopolare Elektroden ø 4mm	HF9899-41			
Monopolare Elektroden ø 4mm	HF9899-42			
Monopolare Elektroden ø 4mm	HF9899-43			
LAP-Elektrode, Spatel	HF9909-40			
LAP-Elektrode,Haken,36cm,4mm	HF9910-40			
LAP-Elektrode,Haken,36cm,4mm	HF9911-40			
LAP-Elektrode,Nadel,36cm,4mm	HF9912-40			
LAP-Elektrode, Spatel	HF9914-40			
LAP-Elektrode, Haken	HF9915-40			
LAP-Elektrode, Haken fein	HF9916-40			
LAP-Elektrode, Nadel	HF9917-40			
LAP-Elektrode, Kugel	HF9918-40			
Monop.Argon-K-Elekt., 73,5,4m	HF9920-40			
Monop.Argon-K-Elekt, 148,5,4mm	HF9921-40			
Monop.Argon-K-Elekt,368,5,4mm	HF9922-40			
Monop.Argon-Schn-Elekt,14mm,4m	HF9923-40			
Monop.Argon-Schn-Elekt, 14mm,4m	HF9924-40			
Monop.Argon-Schn-Elekt,14mm,4m	HF9925-40			
Monop.Argon-Schn-Elekt,14mm,4m	HF9926-40			
Starre Argonkoagulationselek-	HF9927-01			
Starre Argonkoagulationselek-	HF9927-02			
Starre Argonkoagulationselek-	HF9927-03			
Starre Argonkoagulationselek-	HF9927-05			
Starre Argonkoagulationselek-	HF9927-06			
Mono.Wechselelektrode Economy	HF9953-01			
Mono.Wechselelektrode Economy	HF9953-02			
Mono.Wechselelektrode Economy	HF9953-03			
Mono.Wechselelektrode Economy	HF9953-04			
Mono.Wechselelektrode Economy	HF9953-05			
Mono.Wechselelektrode Economy	HF9953-06			
Mono.Wechselelektrode Economy	HF9953-07			
Mono.Wechselelektrode Economy	HF9953-08			
Mono.Wechselelektrode Economy	HF9953-09			
Mono.Wechselelektrode Economy	HF9953-10			
Mono.Wechselelektrode Economy	HF9954-01			
Mono.Wechselelektrode Economy	HF9954-02			
Mono.Wechselelektrode Economy	HF9954-03			



Device name or Basic UDI-DI (under MDR appli- cation)		MDR Device classi- fication (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification
Mono.Wechselelektrode Economy	HF9954-04			
Mono.Wechselelektrode Economy	HF9954-05			
Mono.Wechselelektrode Economy	HF9954-06			
Mono.Wechselelektrode Economy	HF9954-07			
Mono.Wechselelektrode Economy	HF9954-08			
Mono.Wechselelektrode Economy	HF9954-09			
Mono.Wechselelektrode Economy	HF9954-10			
Präparier-Schere gebogen "Met- zenbaum", 5mm, Schaftlänge 330mm, doppelbeweglich	HF9957-01			
Universal-Fasszange, 5mm, Schaftlänge 330mm, doppelbe- weglich	HF9957-02			
Fasszange "Maryland", 5mm, Schaftlänge 330mm, doppelbe- weglich	HF9957-03			
Krallengreifzange, 3x2 Zähne, 5mm, Schaftlänge 330mm, ein- fachbeweglich	HF9957-04			
Fasszange "Schertl", 5mm, Schaft- länge 330mm, doppelbeweglich	HF9957-05			
Dorsey-Darmfasszange, Maul 20mm, 5mm, Schaftlänge 330mm, doppelbeweglich	HF9957-06			
Fasszange mit 2+4 Zähnen, 5mm, Schaftlänge 330mm, doppelbe- weglich	HF9957-07			
Fasszange, 5mm, Schaftlänge 330mm, doppelbeweglich	HF9957-08			
BABCOCK-Klemme, 5mm, Schaft- länge 330mm, doppelbeweglich	HF9957-09			
Fasszange, spitz, kreuzverzahnt, 5mm, Schaftlänge 330mm, ein- fachbeweglich, Maullänge 18mm	HF9957-10			
Mixerfasszange 90°, 5mm, Schaftlänge 330mm, doppelbe- weglich	HF9957-11			
Fasszange mit Reservoir, stumpf, 5mm, Schaftlänge 330mm, doppel- beweglich	HF9957-12			
Atraumatischer Greifer, 5mm, Schaftlänge 330mm, einfachbe- weglich, mit gewellter Zahnung und Reservoir	HF9957-13			
Device 9 (EMD: Z12010902) Basic UDI-DI: 04058368257Z12010902AQ		☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa	☒ N/A or ☐ Identification of the corre- sponding device	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
Monopolare Koagulation-Ab- saugkanüle, ger., 3mm, 150mm	HF9967-03			
Monopolare Koagulation-Ab- saugkanüle, ger., 4mm, 150mm	HF9967-04			



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
Monopolare Koagulation-Ab-saugkanüle, ger., 5mm, 150mm Monopolare Koagulation-Ab-saugkanüle, ger., 3mm, 270mm Monopolare Koagulation-Ab-saugkanüle, ger., 4mm, 270mm Monopolare Koagulation-Ab-saugkanüle, ger., 5mm, 270mm Monopolare Koagulation-Ab-saugkanüle, geb., 3mm, 120mm Monopolare Koagulation-Ab-saugkanüle, geb., 4mm, 120mm Monopolare Koagulation-Ab-saugkanüle, geb., 5mm, 120mm Monopolare Koagulation-Ab-saugkanüle, geb., 3mm, 240mm Monopolare Koagulation-Ab-saugkanüle, geb., 4mm, 240mm Monopolare Koagulation-Ab-saugkanüle, geb., 5mm, 240mm	HF9967-05	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	under MDD/AIMDD Individual Article number:	
	HF9968-03			
	HF9968-04			
	HF9968-05			
	HF9969-03			
	HF9969-04			
	HF9969-05			
	HF9970-03			
	HF9970-04			
	HF9970-05			
Device 10 (EMD: Z12010902) Basic UDI-DI: 04058368260Z120109025C		☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
HBS 100	HF9501			
HBS 100 Varex	HF9503			
HRF 100	HF9504			
HBS 200i x-touch	HF9505			
HBS 300 x-touch	HF9508			
HBS 300i x-touch	HF9509			
HBS 300i x-touch, mit Standard Frontfolie	HF9509/1			
Elektrochirurgiegerät, MBT-1003.4 Embitron, mit Gefäßversiegelung	HF9509/4			
MD 100	HS9501			
HRF 100, Bissinger Design	HS9504/1			
HRF 100 Touch, 100 Watt, 4Mhz, Micromed Design	HS9504/2			
Radiofrequenzgerät 4MHz, Sondermodell SPINENDOS	HS9504/4			
LBS 200i x-touch, zerlegt	HS9505/1			
Elektrochirurgiegerät MDV touch 200	HS9505/2			



Device name or Basic UDI-DI (under MDR appli- cation)		MDR Device classifi- cation (as proposed by the manufacturer and verified during application review)	If the MDR de- vice is a substi- tute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the de- vices under MDR appli- cation, and the NB Iden- tification													
<table><tr><td>MD touch 300</td><td>HS9508</td></tr><tr><td>MDV touch 300</td><td>HS9509</td></tr><tr><td>MDV touch 300, 300 Watt, mit Gefäßversiegelung</td><td>HS9509/1</td></tr><tr><td>Elektrochirurgiegerät, APS300i Endowell, mit Gefäßversiege- lung</td><td>HS9509/3</td></tr><tr><td>Elektrochirurgiegerät LBS 300</td><td>HS9516-00</td></tr><tr><td>Elektrochirurgiegerät LBS 300</td><td>HS9516-01</td></tr></table>	MD touch 300	HS9508	MDV touch 300	HS9509	MDV touch 300, 300 Watt, mit Gefäßversiegelung	HS9509/1	Elektrochirurgiegerät, APS300i Endowell, mit Gefäßversiege- lung	HS9509/3	Elektrochirurgiegerät LBS 300	HS9516-00	Elektrochirurgiegerät LBS 300	HS9516-01					
MD touch 300	HS9508																
MDV touch 300	HS9509																
MDV touch 300, 300 Watt, mit Gefäßversiegelung	HS9509/1																
Elektrochirurgiegerät, APS300i Endowell, mit Gefäßversiege- lung	HS9509/3																
Elektrochirurgiegerät LBS 300	HS9516-00																
Elektrochirurgiegerät LBS 300	HS9516-01																
Device 11 (EMD: Z12010902) Basic UDI-DI: 04058368261Z1201090269 <table><tr><td>HFIT-T Elektrochirurgiegerät</td><td>HF9518</td></tr><tr><td>HEBU HFIT-T Set</td><td>HF9518-00</td></tr><tr><td>LiTT-T Elektrochirurgiegerät</td><td>HS9518</td></tr></table>	HFIT-T Elektrochirurgiegerät	HF9518	HEBU HFIT-T Set	HF9518-00	LiTT-T Elektrochirurgiegerät	HS9518	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123								
HFIT-T Elektrochirurgiegerät	HF9518																
HEBU HFIT-T Set	HF9518-00																
LiTT-T Elektrochirurgiegerät	HS9518																
Device 12 (EMD: Z12010902) Basic UDI-DI: 04058368263Z1201090283 <table><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9943-10</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9945-15</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9945-20</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9946-15</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9946-20</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9946-25</td></tr><tr><td>HEBU HFIT-T Nadelelektrode,</td><td>H9946-30</td></tr></table>	HEBU HFIT-T Nadelelektrode,	H9943-10	HEBU HFIT-T Nadelelektrode,	H9945-15	HEBU HFIT-T Nadelelektrode,	H9945-20	HEBU HFIT-T Nadelelektrode,	H9946-15	HEBU HFIT-T Nadelelektrode,	H9946-20	HEBU HFIT-T Nadelelektrode,	H9946-25	HEBU HFIT-T Nadelelektrode,	H9946-30	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implanta- ble custom-made-de- vice	☒ N/A or ☐ Identification of the corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
HEBU HFIT-T Nadelelektrode,	H9943-10																
HEBU HFIT-T Nadelelektrode,	H9945-15																
HEBU HFIT-T Nadelelektrode,	H9945-20																
HEBU HFIT-T Nadelelektrode,	H9946-15																
HEBU HFIT-T Nadelelektrode,	H9946-20																
HEBU HFIT-T Nadelelektrode,	H9946-25																
HEBU HFIT-T Nadelelektrode,	H9946-30																
Device 13 (EMD: Z12010903) Basic UDI-DI: 04058368256Z120109039V <table><tr><td>Flexible Argon Sonde TBS, ø1,5mm, 1,5m</td><td>HF9928-01</td></tr><tr><td>Flexible Argon Sonde TBS, ø2,3mm, 1,0m</td><td>HF9928-02</td></tr><tr><td>Flexible Argon Sonde GIT, ø2,3mm, 2,2m</td><td>HF9928-03</td></tr></table>	Flexible Argon Sonde TBS, ø1,5mm, 1,5m	HF9928-01	Flexible Argon Sonde TBS, ø2,3mm, 1,0m	HF9928-02	Flexible Argon Sonde GIT, ø2,3mm, 2,2m	HF9928-03	☐ Class III ☐ Class IIb implanta- ble (non-exempted) ☒ Class IIb / Class IIb implantable (ex- empted) ☐ Class IIa	☒ N/A or ☐ Identification of the corre- sponding device	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123								
Flexible Argon Sonde TBS, ø1,5mm, 1,5m	HF9928-01																
Flexible Argon Sonde TBS, ø2,3mm, 1,0m	HF9928-02																
Flexible Argon Sonde GIT, ø2,3mm, 2,2m	HF9928-03																



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
Flexible Argon Sonde GIT, ø3,2mm, 2,2m	HF9928-04	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	under MDD/AIMDD Individual Article number:	
Flexible Argon Sonde TBS, ø1,5mm, 3,0m	HF9928-05			
Flexible Argon Sonde GIT, ø2,3mm, 3,0m	HF9928-06			
Flexible Argon Sonde GIT,	HF9928-07			
Device 14 (EMD: Z12010903) Basic UDI-DI: 04058368262Z1201090378		☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 049044 0016 Rev. 00 NB 0123
HBS 300 x-touch Argon	HF9514			
HBS 300 x-touch Argon Biseal	HF9516			
Argon Modul	HF9523			
Argon Modul Micromed	HF9523/1			
MD 300 touch Argon Biseal	HS9516			
LBS 300 x-touch Argon Biseal	HS9516/2			
Argon Modul Endowell-Design, APS Argon	HS9523/3			
Argon Modul, Embitron, für MBT-1003.4/MBT-1003.5	HS9523/4			

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:

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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-08-07	713337717 713344242 713343811	Initial issue