TÜVNORD

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
No.: 8003060052	medical@tuev-nord.de	- 2236	20 August 2025

Notified Body Confirmation Letter

Reference: Reference: EC-Certificate acc. 93/42/EEC Annex V, 44 235 117868, 8003060052

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has 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 following manufacturer:

FEH GmbH
Am Stadtwalde 15
48432 Rheine
Germany
SRN Number: DE-MF-010935

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,

TÜVNORD i. V.
Digital unterschrieben von Schmidt Caroline
Datum: 2025.08.21 09:30:17 +02'00'

i. V. Caroline Schmidt
Deputy Head of Project Management
BE Medical
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. V.
Digital unterschrieben von Hoy Benjamin
Datum: 2025.08.20 15:41:24 +02'00'

i. V. Dr. Benjamin Hoy
Head of TIC Management
BE Medical
TÜV NORD CERT GmbH
Notified Body for Medical Devices

Table 1: Devices covered by this letter and for which the NB is also 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 at the pre-application stage)	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
Aesculap 115 x 13 x 1,19mm, G222190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap 115 x 13 x 1,45mm, G222390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap 115 x 22 x 1,00mm, G220990	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap 115 x 22 x 1,19mm, G221190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 22 x 1,27mm, G251120	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 100 x 19 x 1,27mm, G252720	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 115 x 22 x 1,19mm steril, G223190S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 115 x 25 x 1,27mm steril, G223291S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 135 x 22 x 1,19mm, G223180	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 50 x 10 x 0,5/0,6 steril, G1263279S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 50 x 15 x 0,5/0,6 steril, G1263439S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 50 x 15 x 0,6/0,8, G12634311	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 50 x 15 x 0,6/0,8mm, G825570	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 50 x 20 x 0,7/0,9 mm steril, G12635613S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 65 x 25 x 0,9mm steril, G826680S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 75 x 15 x 0,5/08mm steril, G2553120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 13 x 1,27 mm steril, G251220S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 13 x 1,27 mm, G251220	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 13 x 1,00mm steril, G251200S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 13 x 1,19mm, G251210	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 19 x 1,27mm, G251720	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 22 x 1,19mm, G251110	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 22 x 1,27mm steril, G251120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 22 x 1,45mm, G251130	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan® 90 x 26 x 1,47mm steril, G251106AS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Aesculap Acculan®115x 25x 1,27mm steril, G25152AS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Aesculap Stichsägeblatt 60 x 0,7/ 0,9mm, G15673413R	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex® 105 x 19 x 1,27mm, steril, G29772linvapexi0S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex® 90 x 13 x 1,27mm steril, G291220S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex® mit Aesculap Zahnung, steril, G21732713RS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex®53 x 10 x 1,10mm, steril, G21752712RS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex®90 x 22 x 1,00mm steril, G291100S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Arthrex®90 x 22 x 1,27mm steril, G291120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Athrex® 90 x 19 x 1,27mm steril, G29172S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
De Soutter® 115 x 22 x 1,00mm, G280990	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
De Soutter® 90 x 22 x 1,27mm, G281290	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
De Soutter® Neu 90 x 18 x 1,27mm steril, G311620S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
De Soutter® NEU 90 x 25 x 1,00mm steril, G311500S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 115 x 13 x 1,19mm, G232190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 115 x 13 x 1,27mm, G232290	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 115 x 22 x 1,00mm steril, G230990S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 115 x 22 x 1,19mm, G231190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 115 x 22 x 1,45mm, G231390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 25,5 x 14 x 0,4/0,6mm steril, G1632404S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 41 x 19,5 x 0,4/0,6mm steril, G1651544S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 13 x 1,27mm steril, G231220S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 22 x 1,00mm steril, G231100S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 22 x 1,00mm, G231100	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 22 x 1,27mm steril, G231120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 25 x 1,27mm steril, G23152TS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 90 x 25,4 x 1,00mm steril, G23150TS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall® 95 x 19,5 x 0,90mm steril, G231450S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Hall®18,5 x 9,5 x 0,4/0,6mm, G1717254	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec 115 x 13 x 1,19mm, G262190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec 115 x 22 x 1,45mm, G261390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Linvatec Hall® 18,5 x 9,5 x 0,4/0,6mm, G142413	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 25,5 x 4,3 x 0,4/0,6mm, G1692140	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 25,5 x 9,5 x 0,4/0,6mm steril, G162790S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 25,5 x 9,5 x 0,4/0,6mm steril, G1632254S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 25,5 x 9,5 x 0,4/0,6mm, G1632254	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 34 x 6 x 0,4/0,6mm, G1645114	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 41 x 14 x 0,4mm steril, G165770S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 41 x 14 x 0,4mm, G165770	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Linvatec Hall® 41 x 9,5 x 0,4/0,6mm, G142470	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Muster Sägeblätter nach Zeichnung, G1000001	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 11mm straight, 5041RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 11mm straight, steril, 5041SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm rounded, 5114RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm rounded, steril, 5114SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm straight, 5116RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm straight, 5115RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm straight, steril, 5115SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 12 x 6mm straight, steril, 5116SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 14mm straight, 5042RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 14mm straight, steril, 5042SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17 x 10mm straight, 5118RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17 x 10mm straight, steril, 5118SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17 x 6mm straight, 5117RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17 x 6mm straight, steril, 5117SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17mm rounded, 5105RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 17mm rounded, steril, 5105SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 18mm straight, 5043RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 18mm straight, steril, 5043SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 21mm rounded, 5106RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Nouvag 21mm rounded, steril, 5106SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 22mm straight, 5044RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 22mm straight, steril, 5044SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 26mm straight, 5045RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 26mm straight, steril, 5045SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 29 x 12mm straight, 5119RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 29 x 12mm straight, steril, 5119SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 10 x 13,3mm, 5094RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 10 x 13,3mm, steril, 5094SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 15 x 13,3mm, 5095RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 15 x 13,3mm, steril, 5095SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 6 x 13,3mm, 5093RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 6 x 13,3mm, steril, 5093SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 6 x 6,3mm, 5100RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 33 x 6 x 6,3mm, steril, 5100SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 10 x 13,3mm, 5097RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 10 x 13,3mm, steril, 5097SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 15 x 13,3mm, 5098RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 15 x 13,3mm, steril, 5098SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 13,3mm, 5096RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 13,3mm, steril, 5096SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 3mm, 5101RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 3mm, steril, 5101SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 6,3mm, 5099RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Nouvag 45 x 6 x 6,3mm, steril, 5099SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Rhino Mikro-Sägeblatt 44 x6 x 0,4mm, 5112RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Rhino Mikro-Sägeblatt 44 x6 x 0,4mm, steril, 5112SNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Set besteh. aus: 5041, 5042, 5043, 5044, 5045, 5049RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Set besteh. aus: 5114, 5115, 5116,5117, 5118, 5119 steril, 5120RNOU	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 115 x 13 x 1,19mm, G242190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 115 x 13 x 1,27mm, G242290	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 115 x 13 x 1,45mm, G242390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 115 x 22 x 1,45mm, G241390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 18 x 5,5 x 0,4/0,6mm steril, G1316104S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 18 x 5,5 x 0,4/0,6mm, G1316104	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 25 x 9 x 0,4/0,6mm, G13302420	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 25 x 9 x 0,4/0,6mm steril, G13302420S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 25 x 9,8 x 0,4/0,6 mm, G1330264	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 31 x 9,0 x 0,4/0,6mm steril, G1344264S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 34,5 x 13 x 0,4/0,5 steril, G1333373AS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 34,5 x 16,5 x 0,4/0,6 mm steril, G1346477AS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 35 x 9 x 0,4/0,4 steril, G1346244S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 40 x 13 x 0,5mm, G134670	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 41 x 19,5 x 0,4/0,4mm steril, G1351544S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® 60 x 14 x 0,4/0,6mm steril, G13674010VS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® plus 125 x 13 x 1,19mm, G252190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® plus 125 x 22 x 1,19mm, G251190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 59 x 29 x 0,65/1,00mm steril, G13677212S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 13 x 1,00 mm steril, G271200S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 13 x 1,00 mm, G271200	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 13 x 1,27mm steril, G271220S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 13 x 1,27mm, G271220	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 17 x 1,27mm steril, G271420S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 19 x 1,27mm, G271720K	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 19 x 1,27mm steril, G271720S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 22 x 1,27mm steril, G271120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Stryker® System S 90 x 22 x 1,27mm, G271120	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 22 x 1,27mm, G-271290	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x 26 x 1,27mm steril, G27162TS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker® System S 90 x13 x1,45, G271230	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker®System S 90 x 13 x 1,27mm, steril, G272290S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Stryker®System S 90 x 22 x 1,47mm steril, G271160S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes Microdrive 13-6-0,25, G206110V	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 80 x 10 x 1,05 mm steril, G2112300RS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 115 x 13 x 1,19mm, G212190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 115 x 22 x 1,00mm, G210990	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 115 x 22 x 1,45mm, G211390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 13,4 x 0,4 x 0,66 mm, G11649V	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 46 x 8 x 1,00mm steril, G11782024RS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 70 x 25,9 x 0,6/0,8 mm, G116540A	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,19mm, G211210	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,27mm steril, G211220S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,27mm, G211220	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,27mm, G212290	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,00mm, G211090	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,19mm steril, G211210S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 13 x 1,45mm, G212390	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 19 x 1,27mm steril, G211720S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 19 x 1,27mm, G211720	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,00mm steril, G211100S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,00mm, G211100	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,19mm steril, G211110S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,19mm, G211110	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,19mm, G211190	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 22 x 1,27mm steril, G211120S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Synthes® 90 x 22 x 1,27mm, G211120	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 25 x 0,89mm steril, G211550AS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® 90 x 25 x 1,27mm steril, G271520S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® AO 70 x 26 x 0,8/1,0 mm, G11726615A	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 15 x 10 x 0,3/0,4 mm, G1810271	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 15 x 6 x 0,3/0,4 mm steril, G1810111S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 17 x 10 x 0,3/0,4 mm steril, G1814271TS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 22 x 8 x 0,3/0,4 mm steril, G1824201S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 22 x 8 x 0,3/0,4 mm, G1824201	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 27 x 10 x 0,3/0,6 mm steril, G18362720VS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 27 x 14 x 0,3/0,6 mm steril, G18364020S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 27 x 14 x 0,3/0,6 mm, G18364020	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 31 x 10 x 0,3/0,4mm, G1844271V	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 31 x 6 x 0,4mm, steril, G1844111VS	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthes® Colibri 50 x14 x 0,3/0,6 mm, steril, G18634023S	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
Synthtes Colibri 50 x 20 x 0,3/0,6 mm, G18635623A	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 26/0,4 mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 22/0,4mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 18/0,4mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 14/0,4mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 11/0,4mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 17mm rounded 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 21mm rounded 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 12 x 4mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 12 x 6mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 12 x 6mm rounded 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 17 x 6mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 17 x 10mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
STM 29 x 12mm straight 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 45 x 6 x 3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 33 x 6 x 6,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 45 x 6 x 6,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 33 x 6 x 13,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 45 x 6 x 13,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 33 x 10 x 13,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 45 x 10 x 13,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert
STM 45 x 15 x 13,3mm 42623537701MR	IIA	N/A	Certificate No. 44 235 117868; TÜV NORD Cert

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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 Wundspreizer 320mm, 50mm tiefe, WS-4013-02	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Adson Wundspreizer m. Gelenk 32cm stumpf, WSS-4013	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Anderson-Adson Wundspreizer 200mm, WSS-4012-02	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Beckmann Wundsperrer 330mm mit Gelenk, WSS-01-234-S	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel 230mm x 3,2mm, WSL-08-407-03	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel, 230mmx 2,2mm, WSL-08.406-10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel, 230mmx 2mm, WSL-08-406-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel, gebogen 45°, WSL-08-410-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel, gebogen 45°, WSL-08-410-30	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Bruns, scharfer Löffel, gebogen 45°, WSL-08-411-03	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Bruns, scharfer Löffel, gerade 230mm, WSL-08-406-30	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Caspar Dissektor 2mm 230mm, WSD-65.122-08	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Caspar Dissektor 4,5mm 230mm, WSD-5.122-04	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cloward Spreizer, WSS 52-11-13-1800	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cobb-Raspatorium 240mm x 13mm, WSR-08.704-13	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cobb-Raspatorium 240mm x 19mm, WSR-08.704-19	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cobb-Raspatorium 280mm x 19mm, WSR-13-512-19	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cushing Nervhäkchen 280mm, 4mm, WSH-10.556-28	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Cushing Nervhäkchen 280mm, WSH-10.557-28	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Dahmen Osteotom 300mm 8mm gerade, WSM-5319-02/08	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Davis Doppeldissektor 24,5cm, WSM-10-522-24/10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Davis Doppeldissektor 32cm, 4,5mm, WSD-10-522-32/10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Davis Doppeldissektor fein/mikro, WSM-10-522-24-4.5	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Dissektionshäkchen 200mm 90° fein, WSH-110.200.90	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Flachmeißel gebogen, 16mm breit, WSM-265-16	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Flachzange, Extraktionszange, WSZ-31-864-18	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Löffelzange PT 11" 5x10mm gerade, WSL-285-FG-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Löffelzange PT 11" 8x12mm gerade, WSL-288-FG-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
FS Löffelzange PT 11" 8x12mm gerade, WSZ-288-FG-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Löffelzange PT 280mm, Maul 4mm x 10mm, WSL-284-FG-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directive
FS Löffelzange PT280mm, Maul 6mm x 12mm, WSL-286-FG-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze 180 x4mm 130° aufw. mod. Griff, WSS-183-SV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze 200mm, 2mm 130° aufw. mod., WSS-202-SV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 11" 3mm 130° aufw.mod.Griff, WSS-283-SV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 11" 6mm 130° aufw.mod.Griff, WSS-286-SV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 230 mm 1,5 mm 130° aufwärts, WSS-2315-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 230 mm 2 mm 130° aufwärts, WSS-232-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 230 x 3 mm 130° aufwärts, WSS-233-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 230mm 1mm 130° aufwärts, WSS-231-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 280mm 2mm 130° aufwärts, WSS-282-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 280mm 3mm 130° aufwärts, WSS-283-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 280mm 4mm 130° aufwärts, WSS-284-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 8" 2mm 130° aufw. mod., WSS-202-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 8" 3mm 130° aufw. mod., WSS-203-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS Stanze PT 8" 5mm 130° aufw. mod., WSS-205-SV-PT/D.S.	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS-Stanze 200mm x 5mm 130° aufw. mod., WSS-205-SV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS-Stanze 230 x 2mm 130° aufw. mod., WSS-232-SV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
FS-Stanze 250x2mm 130°, zerlegbar, WSS-252-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS-Stanze 250x3mm 130°, zerlegbar, WSS-253-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS-Stanze 250x4mm 130°, zerlegbar, WSS-254-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
FS-Stanze PT 11" 5mm 130° aufw.mod.Griff, WSS-285-SV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Gelpi-Spreizer 26 cm, WSS-1260-01	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Gross-Maier Kornzange, gebogen 250mm, WSZ-05-703-25	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Hess Nervwurzelhaken 175mm 5mm, WSH-10.616-05	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Hess Nervwurzelhaken 175mm 7mm, WSH-10.616-07	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Hohlmeißelzange 24cm gebogen, 3mm Smith, WSZ-10-132.24	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Knochenhaltezange, schlankes Modell, WSZ-186.20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Kocher -Langenbeck, 55x11mm, ACH-02.391-07	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Kocher -Langenbeck, 80x16mm, ACH-02.391-10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lambotte-Meißel (Osteotom) 250 x 10mm, WSM-08-280-10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lambotte-Meißel (Osteotom) 250 x 16mm, WSM-08-280-16	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lambotte-Meißel (Osteotom) 250 x 20mm, WSM-08-280-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lambotte-Meißel (Osteotom) 250 x 4mm, WSM-08-280-04	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lambotte-Meißel (Osteotom) 250 x 8mm, WSM-08-280-08	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lamina Spreizer 210mm x 8mm, WS-52-11-23-1802	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Leksell-Stille Hohlmeißelzange 24cm, 6mm, WSZ-10-110.06	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Lexer Flachmeißel 220 x 15mm, gerade, WSM-18-1134-15	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lexer Flachmeißel 220 x10mm gerade, WSM-18-1134-10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Lexer Hohlmeissel 220x15mm AB Klinge 15°, WSM-18-1135-15-PG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Liston Knochensplitterzange 18,5cm, WSM-20-205.18/10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
LK Stanze PT 250mm, 130° aufw. Langhub, WSS-252-KV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
LK Stanze PT 280mm 4mm 130° aufwärts, WSS-284-KV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
LK Stanze PT 280mm 5mm 130° aufwärts, WSS-285-KV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
LK Stanze PT 280mm 6mm 130° aufwärts, WSS-286-KV-PT	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Mikro-Nervhäkchen 240mm 90° abgew. 4mm, WSH-65-118-07	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Nervhäkchen 245mm 90° abgew. 5mm stumpf, WSH-65-121-02-S	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Dahmen 300 x 10mm, gerade, WSM-5319-02/10	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Dahmen 300 x 15mm, gerade, WSM-5319-02/15	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Dahmen 370 x15mm, gerade, WSM-3160-15-370	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Lexer 370 x 20mm gerade, WSM-3160-20-370	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Lexer 370 x 22mm gerade, WSM-3160-22-370	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Osteotom n. Lexer 370 x10mm gerade, WSM-3160-10-370	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
PexieFix® standard, G700500	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Pfriem n. Perthes, 210mm, WS-100.23.120	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Raspatorium gerade Schneide, 185 x 6mm, WSR-16-03-19-1801	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Raspatorium gerundete Schneide,185 x 6mm, WSR-16-03-19-1802	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Raspatorium n. Freer 18,5cm, WSR-1850	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Raspatorium nach Cobb 14 mm, WSR-2462-30	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
REDON GUIDING NEEDLE CHAR: 8, AE-BN942R	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
REDON NADEL CHAR: 6 TROCKARSPITZE, AS.432.06	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Redon-Spieß Ch. 10 gerade, ACPI-10-197	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Redon-Spieß Ch. 22 gebogen, ACPI-22-190	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rongeur 200mm, Maul 2mm x 10mm, WSR-202-CG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rongeur 200mm, Maul 3mm x 10mm, WSR-203-CG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rongeur 200mm, Maul 4mm x 10mm, WSR-204-CG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rongeur 280mm, Maul 3mm x 10mm, WSR-283-CG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Rongeur 280mm, Maul 4mm x 10mm, WSR-284-CG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, 4mm, WSZ-10-108.04	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, 5mm, WSZ-10-108.05	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, 5mm, WSZ-10-111.05	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, 6mm, WSZ-10-108.06	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, 6mm, WSZ-10-131.26	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, WSZ-10-131.04	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Röttgen-Ruskin Hohlmeißelzange 23cm, WSZ-10-131.24	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Scharfes Langes Lig.Flavum-Häckchen, ACH-10.587-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Scharfes Lig. Flavum-Häkchen, WSH-10.587-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Smith-Peterson Hohlmeißelzange 240mm 3mm, WSZ-10-142.24	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Spondy Hohlmeissel 22cm 15mm, WSM-18-1135-15-P	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Spondy Hohlmeissel 22cm 20mm 15° geb., WSM-18-1135-20	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Spondy Hohlmeissel 22cm 20mm, WSM-18-1135-20-P	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Spondy-Hohlmeißel 22cm 15mm 15° geb., WSM-18-1135-15	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stanze Typ Kerrison zerlegbar, 130°, WSS-2325-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stanze, Kerrison-Type, zerlegbar, 130°, WSS-231-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stanze, Kerrison-Type, zerlegbar, 130°, WSS-232-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stanze, Kerrison-Type, zerlegbar, 130°, WSS-233-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stanze, Kerrison-Type, zerlegbar, 130°, WSS-234-KV-PT/D	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Stephen - Haken 110x125x19mm, WSH110.125.19	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Ulrich Kornzange, gerade 250mm, WSZ-05-700-25	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Weitlaner Wundspreizer 19cm, 4x4 Zähne, WSS-4012-B	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wirbelkörperspreizer mit Flügel,, SMS-02-150	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
WS- Spreizer nach "Gelpi", WS-S901.26.01	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
WS-Spreizer nach "Mc Bride", WS-S901.28.01	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wundhäkchen, 140mm, 6x12mm, ACH-02.103-12	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Wundhaken nach ZENKER, 75x12mm, 270mm, ACH-02.396-75	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Wundhaken VOLKMANN 4-zahnig scharf 9X19m, ACH-02325-04	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives
Zwischenwirbel Hohlmeißelzange 24cm, 3mm, WSZ 10-109.24	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025/05/28	Rev00	Initial issue according to the Product list P111-F-007_Rev5_20240529
2025/08/20	Rev01	Correction according to the Product list P111-F-007_Rev5_20250612_Rev2