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

VDW GmbH
Bayerwaldstraße 15
81737 München
GERMANY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
015409	200130017391	medical_device@tuvsud.com	n/a	2025-01-09	1 of 42

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 015409 0038 Rev. 02

Reference: 200130017391

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-000015941

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 (N/A)

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 http: http://www.tuvsud.com/ps-cert?q=cert:CL 015409 0038

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-01-09

TÜV SÜD Product Service GmbH
Medical and Health Services

Thomas Schumacher (16. Januar 2025 09:16 GMT+1)

Thomas Schumacher
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Florian Grentzebach

Florian Grentzebach
Application Reviewer

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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 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
++E22510043DE Device name and article number			☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
ROOT FILLERS -L-, METAL SHANK	V010093021025				
ROOT FILLERS -L-, METAL SHANK	V010093025025				
ROOT FILLERS -L-, METAL SHANK	V010093025030				
ROOT FILLERS -L-, METAL SHANK	V010093025035				
ROOT FILLERS -L-, METAL SHANK	V010093025040				
ROOT FILLERS -L-, METAL SHANK	V010093025290				
ROOT FILLERS -L-, METAL SHANK	V020093021025				
ROOT FILLERS -L-, METAL SHANK	V020093021030				
ROOT FILLERS -L-, METAL SHANK	V020093021035				
ROOT FILLERS -L-, METAL SHANK	V020093021040				
ROOT FILLERS -L-, METAL SHANK	V020093021290				
ROOT FILLERS -L-, METAL SHANK	V020093025025				
ROOT FILLERS -L-, METAL SHANK	V020093025030				
ROOT FILLERS -L-, METAL SHANK	V020093025035				
ROOT FILLERS -L-, METAL SHANK	V020093025040				
ROOT FILLERS -L-, METAL SHANK	V020093025290				
ROOT FILLERS -L-, METAL SHANK	V030093021025				
ROOT FILLERS -L-, METAL SHANK	V030093025025				
ROOT FILLERS -L-, METAL SHANK	V030093025030				
ROOT FILLERS -L-, METAL SHANK	V030093025035				
ROOT FILLERS -L-, METAL SHANK	V030093025040				
ROOT FILLERS -L-, METAL SHANK	V030093025290				
KENDO ROOT FILLER	V200709021025	V201709021025			
KENDO ROOT FILLER	V200709021030	V201709021030			
KENDO ROOT FILLER	V200709021035	V201709021035			
KENDO ROOT FILLER	V200709021040	V201709021040			
KENDO ROOT FILLER	V200709021290	V201709021290			
KENDO ROOT FILLER	V200709025025	V201709025025			
KENDO ROOT FILLER	V200709025030	V201709025030			
KENDO ROOT FILLER	V200709025035	V201709025035			
KENDO ROOT FILLER	V200709025040	V201709025040			
KENDO ROOT FILLER	V200709025290	V201709025290			
PRO-ENDO ROOT FILLER	V200609021025				
PRO-ENDO ROOT FILLER	V200609021030				
PRO-ENDO ROOT FILLER	V200609021035				
PRO-ENDO ROOT FILLER	V200609021040				
PRO-ENDO ROOT FILLER	V200609021290				
PRO-ENDO ROOT FILLER	V200609025025				
PRO-ENDO ROOT FILLER	V200609025030				
PRO-ENDO ROOT FILLER	V200609025035				

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
PRO-ENDO ROOT FILLER V200609025040 PRO-ENDO ROOT FILLER V200609025290			
++E22510046DL Device name and article number VDW.ROTATE DEMO (15.04,20.05,25.06) 25MM MDDVROT325AST VDW.ROTATE ASSORT 3-FILE 21MM MSTVROT321AST VDW.ROTATE ASSORT 3-FILE 25MM MSTVROT325AST VDW.ROTATE ASSORT 3-FILE 31MM MSTVROT331AST VDW.ROTATE 15.04 4-FILES 21MM MSTVROT421415 VDW.ROTATE 25.04 4-FILES 21MM MSTVROT421425 VDW.ROTATE 30.04 4-FILES 21MM MSTVROT421430 VDW.ROTATE 35.04 4-FILES 21MM MSTVROT421435 VDW.ROTATE 40.04 4-FILES 21MM MSTVROT421440 VDW.ROTATE 50.04 4-FILES 21MM MSTVROT421450 VDW.ROTATE 60.04 4-FILES 21MM MSTVROT421460 VDW.ROTATE 20.05 4-FILES 21MM MSTVROT421520 VDW.ROTATE 25.05 RETREATM. 4-FILES 21MM MSTVROT421525 VDW.ROTATE 25.06 4-FILES 21MM MSTVROT421625 VDW.ROTATE 30.06 4-FILES 21MM MSTVROT421630 VDW.ROTATE 35.06 4-FILES 21MM MSTVROT421635 VDW.ROTATE 40.06 4-FILES 21MM MSTVROT421640 VDW.ROTATE 15.04 4-FILES 25MM MSTVROT425415 VDW.ROTATE 25.04 4-FILES 25MM MSTVROT425425 VDW.ROTATE 30.04 4-FILES 25MM MSTVROT425430 VDW.ROTATE 35.04 4-FILES 25MM MSTVROT425435 VDW.ROTATE 40.04 4-FILES 25MM MSTVROT425440 VDW.ROTATE 50.04 4-FILES 25MM MSTVROT425450 VDW.ROTATE 60.04 4-FILES 25MM MSTVROT425460 VDW.ROTATE 20.05 4-FILES 25MM MSTVROT425520 VDW.ROTATE 25.06 4-FILES 25MM MSTVROT425625 VDW.ROTATE 30.06 4-FILES 25MM MSTVROT425630 VDW.ROTATE 35.06 4-FILES 25MM MSTVROT425635 VDW.ROTATE 40.06 4-FILES 25MM MSTVROT425640 VDW.ROTATE FILES ONLY TRAINING MSTVROT425ATK VDW.ROTATE 15.04 4-FILES 31MM MSTVROT431415 VDW.ROTATE 25.04 4-FILES 31MM MSTVROT431425 VDW.ROTATE 30.04 4-FILES 31MM MSTVROT431430 VDW.ROTATE 35.04 4-FILES 31MM MSTVROT431435 VDW.ROTATE 40.04 4-FILES 31MM MSTVROT431440 VDW.ROTATE 50.04 4-FILES 31MM MSTVROT431450 VDW.ROTATE 60.04 4-FILES 31MM MSTVROT431460 VDW.ROTATE 20.05 4-FILES 31MM MSTVROT431520 VDW.ROTATE 25.06 4-FILES 31MM MSTVROT431625 VDW.ROTATE 30.06 4-FILES 31MM MSTVROT431630 VDW.ROTATE 35.06 4-FILES 31MM MSTVROT431635 VDW.ROTATE 40.06 4-FILES 31MM MSTVROT431640	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
VDW.ROTATE 15.04 6-FILES 21MM	MSTVROT621415			
VDW.ROTATE 25.04 6-FILES 21MM	MSTVROT621425			
VDW.ROTATE 30.04 6-FILES 21MM	MSTVROT621430			
VDW.ROTATE 35.04 6-FILES 21MM	MSTVROT621435			
VDW.ROTATE 40.04 6-FILES 21MM	MSTVROT621440			
VDW.ROTATE 50.04 6-FILES 21MM	MSTVROT621450			
VDW.ROTATE 60.04 6-FILES 21MM	MSTVROT621460			
VDW.ROTATE 20.05 6-FILES 21MM	MSTVROT621520			
VDW.ROTATE 25.05 RETREATM. 6-FILES 21MM	MSTVROT621525			
VDW.ROTATE 25.06 6-FILES 21MM	MSTVROT621625			
VDW.ROTATE 30.06 6-FILES 21MM	MSTVROT621630			
VDW.ROTATE 35.06 6-FILES 21MM	MSTVROT621635			
VDW.ROTATE 40.06 6-FILES 21MM	MSTVROT621640			
VDW.ROTATE 15.04 6-FILES 25MM	MSTVROT625415			
VDW.ROTATE 25.04 6-FILES 25MM	MSTVROT625425			
VDW.ROTATE 30.04 6-FILES 25MM	MSTVROT625430			
VDW.ROTATE 35.04 6-FILES 25MM	MSTVROT625435			
VDW.ROTATE 40.04 6-FILES 25MM	MSTVROT625440			
VDW.ROTATE 50.04 6-FILES 25MM	MSTVROT625450			
VDW.ROTATE 60.04 6-FILES 25MM	MSTVROT625460			
VDW.ROTATE 20.05 6-FILES 25MM	MSTVROT625520			
VDW.ROTATE 25.06 6-FILES 25MM	MSTVROT625625			
VDW.ROTATE 30.06 6-FILES 25MM	MSTVROT625630			
VDW.ROTATE 35.06 6-FILES 25MM	MSTVROT625635			
VDW.ROTATE 40.06 6-FILES 25MM	MSTVROT625640			
VDW.ROTATE 15.04 6-FILES 31MM	MSTVROT631415			
VDW.ROTATE 25.04 6-FILES 31MM	MSTVROT631425			
VDW.ROTATE 30.04 6-FILES 31MM	MSTVROT631430			
VDW.ROTATE 35.04 6-FILES 31MM	MSTVROT631435			
VDW.ROTATE 40.04 6-FILES 31MM	MSTVROT631440			
VDW.ROTATE 50.04 6-FILES 31MM	MSTVROT631450			
VDW.ROTATE 60.04 6-FILES 31MM	MSTVROT631460			
VDW.ROTATE 20.05 6-FILES 31MM	MSTVROT631520			
VDW.ROTATE 25.06 6-FILES 31MM	MSTVROT631625			
VDW.ROTATE 30.06 6-FILES 31MM	MSTVROT631630			
VDW.ROTATE 35.06 6-FILES 31MM	MSTVROT631635			
VDW.ROTATE 40.06 6-FILES 31MM	MSTVROT631640			
++E22510035DF Device name and article number		☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
M2 BASIC SEQ, 4X,10/04 - 25/06	V040007021701			
M2 BASIC SEQ, 4X,30/05 - 25/07	V040007021702			
M2 ASS.,4X,AT21, 10/04 - 25/06	V040007025701			
M2 BASIC SEQ, 4X,30/05 - 25/07	V040007025702			
M2 ASS.,4X,AT16, 10/04 - 25/06	V040007025711			
M2 BASIC SEQ, 4X,10/04 - 25/06	V040007031701			

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
M2 BASIC SEQ, 4X,30/05 - 25/07	V040007031702	implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021010			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021035			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021040			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021045			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021050			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204021060			
M2 NITI TAPER .04 STERILE WP16, 4X	V040204025010			
M2 NITI TAPER .05 STERILE WP16, 4X	V040205021015			
M2 NITI TAPER .05 STERILE WP16, 4X	V040205021030			
M2 NITI TAPER .05 STERILE WP16, 4X	V040205025015			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206021020			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206021025			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206021030			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206021035			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206021040			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206025020			
M2 NITI TAPER .06 STERILE WP16, 4X	V040206025025			
M2 NITI TAPER .07 STERILE WP16, 4X	V040207021025			
M2 NITI ASS. 015/.05 - 040/.04	V040230021230			
M2 NITI ASS. 010/.04 - 020/.06	V040230021456			
M2 NITI ASS. 025/.06 - 040/.04	V040230021457			
M2 NITI ASS. 015/.05 - 040/.04	V040230025230			
M2 NITI ASS. 010/.04 - 020/.06	V040230025456			
M2 NITI ASS. 025/.06 - 040/.04	V040230025457			
M2 RETREATMENT FILES, STERILE	V040232021015			
M2 RETREATMENT FILES, STERILE	V040232021025			
M2 RETREATMENT FILES, STERILE	V040232021202			
M2 NITI TAPER .04 STERILE WP16	V040234021010			
M2 NITI TAPER .04 STERILE WP16	V040234021035			
M2 NITI TAPER .04 STERILE WP16	V040234021040			
M2 NITI TAPER .04 STERILE WP16	V040234021045			
M2 NITI TAPER .04 STERILE WP16	V040234021050			
M2 NITI TAPER .04 STERILE WP16	V040234021060			
M2 NITI TAPER .04 STERILE WP16	V040234025010			
M2 NITI TAPER .04 STERILE WP16	V040234025035			
M2 NITI TAPER .04 STERILE WP16	V040234025040			
M2 NITI TAPER .04 STERILE WP16	V040234025045			
M2 NITI TAPER .04 STERILE WP16	V040234025050			
M2 NITI TAPER .04 STERILE WP16	V040234025060			
M2 NITI ASS. 045/.04 - 060/.04	V040234025246			
M2 NITI TAPER .05 STERILE WP16	V040235021015			
M2 NITI TAPER .05 STERILE WP16	V040235021030			
M2 NITI TAPER .05 STERILE WP16	V040235025015			
M2 NITI TAPER .05 STERILE WP16	V040235025030			
M2 NITI TAPER .06 STERILE WP16	V040236021020			

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
M2 NITI TAPER .06 STERILE WP16	V040236021025			
M2 NITI TAPER .06 STERILE WP16	V040236021030			
M2 NITI TAPER .06 STERILE WP16	V040236021035			
M2 NITI TAPER .06 STERILE WP16	V040236021040			
M2 NITI TAPER .06 STERILE WP16	V040236025020			
M2 NITI TAPER .06 STERILE WP16	V040236025025			
M2 NITI TAPER .06 STERILE WP16	V040236025030			
M2 NITI TAPER .06 STERILE WP16	V040236025035			
M2 NITI TAPER .06 STERILE WP16	V040236025040			
M2 NITI ASS. 030/.06 - 040/.06	V040236025203			
M2 NITI TAPER .07 STERILE WP16	V040237021025			
M2 NITI TAPER .07 STERILE WP16	V040237025025			
M2 NITI TAPER .04 STERILE WP21, 4X	V041204025010			
M2 NITI TAPER .05 STERILE WP21, 4X	V041205025015			
M2 NITI TAPER .06 STERILE WP21, 4X	V041206025020			
M2 NITI TAPER .06 STERILE WP21, 4X	V041206025025			
M2 NITI ASS.010/04-020/06 WP21	V041230025456			
M2 NITI ASS.025/06-040/04 WP21	V041230025457			
M2 NITI TAPER .04 STERILE WP21	V041234025010			
M2 NITI TAPER .04 STERILE WP21	V041234031010			
M2 NITI TAPER .04 STERILE WP21	V041234031035			
M2 NITI TAPER .04 STERILE WP21	V041234031040			
M2 NITI TAPER .04 STERILE WP21	V041234031045			
M2 NITI TAPER .04 STERILE WP21	V041234031050			
M2 NITI TAPER .04 STERILE WP21	V041234031060			
M2 NITI TAPER .05 STERILE WP21	V041235025015			
M2 NITI TAPER .05 STERILE WP21	V041235031015			
M2 NITI TAPER .05 STERILE WP21	V041235031030			
M2 NITI TAPER .06 STERILE WP21	V041236025020			
M2 NITI TAPER .06 STERILE WP21	V041236025025			
M2 NITI TAPER .06 STERILE WP21	V041236031020			
M2 NITI TAPER .06 STERILE WP21	V041236031025			
M2 NITI TAPER .06 STERILE WP21	V041236031030			
M2 NITI TAPER .06 STERILE WP21	V041236031035			
M2 NITI TAPER .06 STERILE WP21	V041236031040			
M2 NITI TAPER .07 STERILE WP21	V041237031025			
++E22510042DC Device name and article number		☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
RECIPROC FILES 4X	V040012021025			
RECIPROC FILES 4X	V040012021040			
RECIPROC FILES 4X	V040012021050			
RECIPROC FILES 4X	V040012021200			
RECIPROC FILES 4X	V040012025025			
RECIPROC FILES 4X	V040012025040			
RECIPROC FILES 4X	V040012025050			
RECIPROC FILES 4X	V040012025200			

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
RECIPROC FILES 4X	V040012031025 V040012031040 V040012031050 V040212021025 V040212021040 V040212021050 V040212021233 V040212025025 V040212025040 V040212025050 V040212025233 V040212031025 V040212031040 V040212031050 V040212031233 V040052021025 V040052021040 V040052021050 V040052021200 V040052025025 V040052025040 V040052025050 V040052025200 V040052031025 V040052031040 V040052031050 V040252021025 V040252021040 V040252021050 V040252025025 V040252025040 V040252025050 V040252031025 V040252031040 V040252031050	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++E22510045DJ Device name and article number R-PILOT, 4X, STERILE R-PILOT, 4X, STERILE R-PILOT, 4X, STERILE R-PILOT, 6X, STERILE R-PILOT, 6X, STERILE R-PILOT, 6X, STERILE	 V041217021012 V041217025012 V041217031012 V040217021012 V040217025012 V040217031012	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++E22510023D8 Device name and article number: BARBED BROACHES STERILE CC-C. V040333021410 BARBED BROACHES STERILE CC-C. V040333021420 BARBED BROACHES STERILE CC-C. V040333021430 BARBED BROACHES STERILE CC-C. V040333021440 BARBED BROACHES STERILE CC-C. V040333021450 BARBED BROACHES STERILE CC-C. V040333021460 BARBED BROACHES STERILE CC-C. V040333021470 BARBED BROACHES STERILE CC-C. V040333021480 BARBED BROACHES STERILE CC-C. V040333021485	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
++E22510028DJ Device name and article number: FLEXMASTER TAPER 02 STERILE V040341021015 FLEXMASTER TAPER 02 STERILE V040341021020 FLEXMASTER TAPER 02 STERILE V040341021025 FLEXMASTER TAPER 02 STERILE V040341021030 FLEXMASTER TAPER 02 STERILE V040341021035 FLEXMASTER TAPER 02 STERILE V040341021040 FLEXMASTER TAPER 02 STERILE V040341021045 FLEXMASTER TAPER 02 STERILE V040341021241 FLEXMASTER TAPER 02 STERILE V040341025015 FLEXMASTER TAPER 02 STERILE V040341025020 FLEXMASTER TAPER 02 STERILE V040341025025	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
FLEXMASTER TAPER 02 STERILE	V040341025030	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
FLEXMASTER TAPER 02 STERILE	V040341025035			
FLEXMASTER TAPER 02 STERILE	V040341025040			
FLEXMASTER TAPER 02 STERILE	V040341025045			
FLEXMASTER TAPER 02 STERILE	V040341025050			
FLEXMASTER TAPER 02 STERILE	V040341025060			
FLEXMASTER TAPER 02 STERILE	V040341025070			
FLEXMASTER TAPER 02 STERILE	V040341025231			
FLEXMASTER TAPER 02 STERILE	V040341031231			
FLEXMASTER TAPER 04 STERILE	V040342021015			
FLEXMASTER TAPER 04 STERILE	V040342021020			
FLEXMASTER TAPER 04 STERILE	V040342021025			
FLEXMASTER TAPER 04 STERILE	V040342021030			
FLEXMASTER TAPER 04 STERILE	V040342021035			
FLEXMASTER TAPER 04 STERILE	V040342021040			
FLEXMASTER TAPER 04 STERILE	V040342025015			
FLEXMASTER TAPER 04 STERILE	V040342025020			
FLEXMASTER TAPER 04 STERILE	V040342025025			
FLEXMASTER TAPER 04 STERILE	V040342025030			
FLEXMASTER TAPER 04 STERILE	V040342025035			
FLEXMASTER TAPER 04 STERILE	V040342025040			
FLEXMASTER TAPER 04 STERILE	V040342031020			
FLEXMASTER TAPER 04 STERILE	V040342031025			
FLEXMASTER TAPER 04 STERILE	V040342031030			
FLEXMASTER TAPER 04 STERILE	V040342031035			
FLEXMASTER TAPER 04 STERILE	V040342031040			
FLEXMASTER TAPER 06 STERILE	V040343021015			
FLEXMASTER TAPER 06 STERILE	V040343021020			
FLEXMASTER TAPER 06 STERILE	V040343021025			
FLEXMASTER TAPER 06 STERILE	V040343021030			
FLEXMASTER TAPER 06 STERILE	V040343021035			
FLEXMASTER TAPER 06 STERILE	V040343021040			
FLEXMASTER TAPER 06 STERILE	V040343025015			
FLEXMASTER TAPER 06 STERILE	V040343025020			
FLEXMASTER TAPER 06 STERILE	V040343025025			
FLEXMASTER TAPER 06 STERILE	V040343025030			
FLEXMASTER TAPER 06 STERILE	V040343025035			
FLEXMASTER TAPER 06 STERILE	V040343025040			
FLEXMASTER ASS.TAP04+06 STERIL	V040344025232			
FLEXMASTER INTRO FILE, STERILE	V040357019000			
++E22510044DG Device name and article number:		☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
ROOT FILLERS -L-, STERILE	V040393021025			
ROOT FILLERS -L-, STERILE	V040393021030			
ROOT FILLERS -L-, STERILE	V040393021035			
ROOT FILLERS -L-, STERILE	V040393021040			

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
ROOT FILLERS -L-, STERILE ROOT FILLERS -L-, STERILE ROOT FILLERS -L-, STERILE ROOT FILLERS -L-, STERILE ROOT FILLERS -L-, STERILE ROOT FILLERS -L-, STERILE	V040393021290 V040393025025 V040393025030 V040393025035 V040393025040 V040393025290	☐ 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		
++E22510031D7 Device name and article number: RECIPROC GUTTA-PERCHA RECIPROC GUTTA-PERCHA RECIPROC GUTTA-PERCHA RECIPROC GUTTA-PERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA MTWO GUTTAPERCHA ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .04 ALPHA-GUTTAPERCHA, TAPER .06 ALPHA-GUTTAPERCHA, TAPER .06 ALPHA-GUTTAPERCHA, TAPER .06 ALPHA-GUTTAPERCHA, TAPER .06 ALPHA-GUTTAPERCHA, TAPER .06	V040214028025 V040214028040 V040214028050 V040214028237 V040220028457 V040220428035 V040220428040 V040220428045 V040220428050 V040220428060 V040220528030 V040220628025 V040220628030 V040220628035 V040220628040 V040220728025 V040521028015 V040521028020 V040521028025 V040521028030 V040521028035 V040521028040 V040521028230 V040522028015 V040522028020 V040522028025 V040522028030 V040522028035	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
ALPHA-GUTTAPERCHA, TAPER .06	V040522028040			
ALPHA-GUTTAPERCHA, TAPER .06	V040522028230			
++E22510049DS Device name and article number:		☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
GUTTAPERCHA POINTS, STANDARD.	V010525028015			
GUTTAPERCHA POINTS, STANDARD.	V010525028020			
GUTTAPERCHA POINTS, STANDARD.	V010525028025			
GUTTAPERCHA POINTS, STANDARD.	V010525028030			
GUTTAPERCHA POINTS, STANDARD.	V010525028035			
GUTTAPERCHA POINTS, STANDARD.	V010525028040			
GUTTAPERCHA POINTS, STANDARD.	V010525028045			
GUTTAPERCHA POINTS, STANDARD.	V010525028050			
GUTTAPERCHA POINTS, STANDARD.	V010525028055			
GUTTAPERCHA POINTS, STANDARD.	V010525028060			
GUTTAPERCHA POINTS, STANDARD.	V010525028070			
GUTTAPERCHA POINTS, STANDARD.	V010525028080			
GUTTAPERCHA POINTS 015-040	V010525028230			
GUTTAPERCHA POINTS 045-080	V010525028240			
GUTTAPERCHA POINTS 090-140	V010525028260			
.04 TAPERED GUTTAPERCHA	V010528028015			
.04 TAPERED GUTTAPERCHA	V010528028020			
.04 TAPERED GUTTAPERCHA	V010528028025			
.04 TAPERED GUTTAPERCHA	V010528028030			
.04 TAPERED GUTTAPERCHA	V010528028035			
.04 TAPERED GUTTAPERCHA	V010528028040			
.04 TAPERED GUTTAPERCHA	V010528028230			
.06 TAPERED GUTTAPERCHA	V010529028015			
.06 TAPERED GUTTAPERCHA	V010529028020			
.06 TAPERED GUTTAPERCHA	V010529028025			
.06 TAPERED GUTTAPERCHA	V010529028030			
.06 TAPERED GUTTAPERCHA	V010529028035			
.06 TAPERED GUTTAPERCHA	V010529028040			
.06 TAPERED GUTTAPERCHA	V010529028230			
PUNTAS PIRATAS G.P., SHORT	V010542020431			
PUNTAS PIRATAS G.P., SHORT	V010542020441			
PUNTAS PIRATAS G.P., SHORT	V010542020451			
PUNTAS PIRATAS G.P., SHORT	V010542020461			
PUNTAS PIRATAS G.P., SHORT	V010542020471			
PUNTAS PIRATAS G.P., XF- L	V010542020477			
GUTTAPERCHA POINTS, STANDARD.	V020525028015			
GUTTAPERCHA POINTS, STANDARD.	V020525028020			
GUTTAPERCHA POINTS, STANDARD.	V020525028025			
GUTTAPERCHA POINTS, STANDARD.	V020525028030			
GUTTAPERCHA POINTS, STANDARD.	V020525028035			
GUTTAPERCHA POINTS, STANDARD.	V020525028040			
GUTTAPERCHA POINTS, STANDARD.	V020525028045			

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
GUTTAPERCHA POINTS, STANDARD.	V020525028050			
GUTTAPERCHA POINTS, STANDARD.	V020525028055			
GUTTAPERCHA POINTS, STANDARD.	V020525028060			
GUTTAPERCHA POINTS, STANDARD.	V020525028070			
GUTTAPERCHA POINTS, STANDARD.	V020525028080			
GUTTAPERCHA POINTS 015-040	V020525028230			
GUTTAPERCHA POINTS 045-080	V020525028240			
GUTTAPERCHA POINTS 090-140	V020525028260			
.04 TAPERED GUTTAPERCHA	V020528028015			
.04 TAPERED GUTTAPERCHA	V020528028020			
.04 TAPERED GUTTAPERCHA	V020528028025			
.04 TAPERED GUTTAPERCHA	V020528028030			
.04 TAPERED GUTTAPERCHA	V020528028035			
.04 TAPERED GUTTAPERCHA	V020528028040			
.04 TAPERED GUTTAPERCHA	V020528028230			
.06 TAPERED GUTTAPERCHA	V020529028015			
.06 TAPERED GUTTAPERCHA	V020529028020			
.06 TAPERED GUTTAPERCHA	V020529028025			
.06 TAPERED GUTTAPERCHA	V020529028030			
.06 TAPERED GUTTAPERCHA	V020529028035			
.06 TAPERED GUTTAPERCHA	V020529028040			
.06 TAPERED GUTTAPERCHA	V020529028230			
PUNTAS PIRATAS G.P., SHORT	V020542020431			
PUNTAS PIRATAS G.P., SHORT	V020542020441			
PUNTAS PIRATAS G.P., SHORT	V020542020451			
PUNTAS PIRATAS G.P., SHORT	V020542020461			
PUNTAS PIRATAS G.P., SHORT	V020542020471			
PUNTAS PIRATAS G.P., XF- L	V020542020477			
GUTTAPERCHA POINTS, STANDARD.	V030525028015			
GUTTAPERCHA POINTS, STANDARD.	V030525028020			
GUTTAPERCHA POINTS, STANDARD.	V030525028025			
GUTTAPERCHA POINTS, STANDARD.	V030525028030			
GUTTAPERCHA POINTS, STANDARD.	V030525028035			
GUTTAPERCHA POINTS, STANDARD.	V030525028040			
GUTTAPERCHA POINTS, STANDARD.	V030525028045			
GUTTAPERCHA POINTS, STANDARD.	V030525028050			
GUTTAPERCHA POINTS, STANDARD.	V030525028055			
GUTTAPERCHA POINTS, STANDARD.	V030525028060			
GUTTAPERCHA POINTS, STANDARD.	V030525028070			
GUTTAPERCHA POINTS, STANDARD.	V030525028080			
GUTTAPERCHA POINTS 015-040	V030525028230			
GUTTAPERCHA POINTS 045-080	V030525028240			
GUTTAPERCHA POINTS 090-140	V030525028260			
.04 TAPERED GUTTAPERCHA	V030528028015			
.04 TAPERED GUTTAPERCHA	V030528028020			
.04 TAPERED GUTTAPERCHA	V030528028025			

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
.04 TAPERED GUTTAPERCHA	V030528028030			
.04 TAPERED GUTTAPERCHA	V030528028035			
.04 TAPERED GUTTAPERCHA	V030528028040			
.04 TAPERED GUTTAPERCHA	V030528028230			
.06 TAPERED GUTTAPERCHA	V030529028015			
.06 TAPERED GUTTAPERCHA	V030529028020			
.06 TAPERED GUTTAPERCHA	V030529028025			
.06 TAPERED GUTTAPERCHA	V030529028030			
.06 TAPERED GUTTAPERCHA	V030529028035			
.06 TAPERED GUTTAPERCHA	V030529028040			
.06 TAPERED GUTTAPERCHA	V030529028230			
PUNTAS PIRATAS G.P., SHORT	V030542020431			
PUNTAS PIRATAS G.P., SHORT	V030542020441			
PUNTAS PIRATAS G.P., SHORT	V030542020451			
PUNTAS PIRATAS G.P., SHORT	V030542020461			
PUNTAS PIRATAS G.P., SHORT	V030542020471			
PUNTAS PIRATAS G.P., XF- L	V030542020477			
++E22510050DB Device name and article number: RECIPROC BLUE GUTTAPERCHA RECIPROC BLUE GUTTAPERCHA RECIPROC BLUE GUTTAPERCHA RECIPROC BLUE GUTTAPERCHA VDW.ROTATE GUTTA-PERCHA ISO 25.04 VDW.ROTATE GUTTA-PERCHA ISO 30.04 VDW.ROTATE GUTTA-PERCHA ISO 35.04 VDW.ROTATE GUTTA-PERCHA ISO 40.04 VDW.ROTATE GUTTA-PERCHA ISO 50.04 VDW.ROTATE GUTTA-PERCHA ISO 25.06 VDW.ROTATE GUTTA-PERCHA ISO 30.06 VDW.ROTATE GUTTA-PERCHA ISO 35.06 VDW.ROTATE GUTTA-PERCHA ISO 40.06 VDW.ROTATE GUTTA-PERCHA ISO AST	 V040258028025 V040258028040 V040258028050 V040258028237 M00VRGPF00425 M00VRGPF00430 M00VRGPF00435 M00VRGPF00440 M00VRGPF00450 M00VRGPF00625 M00VRGPF00630 M00VRGPF00635 M00VRGPF00640 M00VRGPF00AST	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
++E22510038DM Device name and article number: RECIPROC PAPER POINTS, STERILE RECIPROC PAPER POINTS, STERILE RECIPROC PAPER POINTS, STERILE RECIPROC PAPER POINTS, STERILE RECIPROC BLUE PAPER POINTS	 V040216029025 V040216029040 V040216029050 V040216029237 V040259029025	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
RECIPROC BLUE PAPER POINTS	V040259029040	implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
RECIPROC BLUE PAPER POINTS	V040259029050			
RECIPROC BLUE PAPER POINTS	V040259029237			
VDW.ROTATE PAPER POINTS ISO 25.04	MSTVRPPO00425			
VDW.ROTATE PAPER POINTS ISO 30.04	MSTVRPPO00430			
VDW.ROTATE PAPER POINTS ISO 35.04	MSTVRPPO00435			
VDW.ROTATE PAPER POINTS ISO 40.04	MSTVRPPO00440			
VDW.ROTATE PAPER POINTS ISO 50.04	MSTVRPPO00450			
VDW.ROTATE PAPER POINTS ISO 60.04	MSTVRPPO00460			
VDW.ROTATE PAPER POINTS ISO 25.06	MSTVRPPO00625			
VDW.ROTATE PAPER POINTS ISO 30.06	MSTVRPPO00630			
VDW.ROTATE PAPER POINTS ISO 35.06	MSTVRPPO00635			
VDW.ROTATE PAPER POINTS ISO 40.06	MSTVRPPO00640			
VDW.ROTATE PAPER POINTS AST	MSTVRPPO00AT			
MTWO PAPERPOINTS 25/.06-25/.07	V040225029457			
MTWO PAPERPOINTS 35/.04 STERILE	V040225429035			
MTWO PAPERPOINTS 40/.04STERILE	V040225429040			
MTWO PAPERPOINTS 45/.04STERILE	V040225429045			
MTWO PAPERPOINTS 50/.04STERILE	V040225429050			
MTWO PAPERPOINTS 60/.04STERILE	V040225429060			
MTWO PAPERPOINTS 30/.05STERILE	V040225529030			
MTWO PAPERPOINTS 25/.06STERILE	V040225629025			
MTWO PAPERPOINTS 30/.06STERILE	V040225629030			
MTWO PAPERPOINTS 35/.06STERILE	V040225629035			
MTWO PAPERPOINTS 40/.06STERILE	V040225629040			
MTWO PAPERPOINTS 25/.07STERILE	V040225729025			
PAPER POINTS, BLISTER, STERILE	V010560029015			
PAPER POINTS, BLISTER, STERILE	V010560029020			
PAPER POINTS, BLISTER, STERILE	V010560029025			
PAPER POINTS, BLISTER, STERILE	V010560029030			
PAPER POINTS, BLISTER, STERILE	V010560029035			
PAPER POINTS, BLISTER, STERILE	V010560029040			
PAPER POINTS, BLISTER, STERILE	V010560029045			
PAPER POINTS, BLISTER, STERILE	V010560029050			
PAPER POINTS, BLISTER, STERILE	V010560029055			
PAPER POINTS, BLISTER, STERILE	V010560029060			
PAPER POINTS, BLISTER, STERILE	V010560029070			
PAPER POINTS, BLISTER, STERILE	V010560029080			
PAPER POINTS, BLISTER, STERILE	V010560029230			
PAPER POINTS, BLISTER, STERILE	V010560029240			
PAPER POINTS, BLISTER, STERILE	V010560029260			
PAPER POINTS, BLISTER, STERILE	V020560029015			
PAPER POINTS, BLISTER, STERILE	V020560029020			
PAPER POINTS, BLISTER, STERILE	V020560029025			
PAPER POINTS, BLISTER, STERILE	V020560029030			
PAPER POINTS, BLISTER, STERILE	V020560029035			

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
PAPER POINTS, BLISTER, STERILE	V020560029040			
PAPER POINTS, BLISTER, STERILE	V020560029045			
PAPER POINTS, BLISTER, STERILE	V020560029050			
PAPER POINTS, BLISTER, STERILE	V020560029055			
PAPER POINTS, BLISTER, STERILE	V020560029060			
PAPER POINTS, BLISTER, STERILE	V020560029070			
PAPER POINTS, BLISTER, STERILE	V020560029080			
PAPER POINTS, BLISTER, STERILE	V020560029230			
PAPER POINTS, BLISTER, STERILE	V020560029240			
PAPER POINTS, BLISTER, STERILE	V020560029260			
PAPER POINTS, BLISTER, STERILE	V030560029015			
PAPER POINTS, BLISTER, STERILE	V030560029020			
PAPER POINTS, BLISTER, STERILE	V030560029025			
PAPER POINTS, BLISTER, STERILE	V030560029030			
PAPER POINTS, BLISTER, STERILE	V030560029035			
PAPER POINTS, BLISTER, STERILE	V030560029040			
PAPER POINTS, BLISTER, STERILE	V030560029045			
PAPER POINTS, BLISTER, STERILE	V030560029050			
PAPER POINTS, BLISTER, STERILE	V030560029055			
PAPER POINTS, BLISTER, STERILE	V030560029060			
PAPER POINTS, BLISTER, STERILE	V030560029070			
PAPER POINTS, BLISTER, STERILE	V030560029080			
PAPER POINTS, BLISTER, STERILE	V030560029230			
PAPER POINTS, BLISTER, STERILE	V030560029240			
PAPER POINTS, BLISTER, STERILE	V030560029260			
++E22510036DH Device name and article number: GUTTAFUSION PINK RECIPROC OBT. R25, 6X GUTTAFUSION PINK RECIPROC OBT. R40, 6X GUTTAFUSION PINK RECIPROC OBT. R50, 6X GUTTAFUSION PINK RECIPROC OBT. R25;30X GUTTAFUSION PINK RECIPROC OBT. R40;30X GUTTAFUSION PINK RECIPROC OBT. R50;30X GUTTAFUSION FOR RECIPROC BLUE, 6 PACK GUTTAFUSION FOR RECIPROC BLUE, 6 PACK GUTTAFUSION FOR RECIPROC BLUE, 6 PACK GUTTAFUSION FOR RECIPROC BLUE, 30 PACK GUTTAFUSION FOR RECIPROC BLUE, 30 PACK GUTTAFUSION FOR RECIPROC BLUE, 30 PACK GUTTAFUSION PINK OBTURATOR 20; 6 PCS GUTTAFUSION PINK OBTURATOR 25; 6 PCS GUTTAFUSION PINK OBTURATOR 30; 6 PCS GUTTAFUSION PINK OBTURATOR 35; 6 PCS GUTTAFUSION PINK OBTURATOR 40; 6 PCS GUTTAFUSION PINK OBTURATOR 45; 6 PCS GUTTAFUSION PINK OBTURATOR 50; 6 PCS	 V041531000025 V041531000040 V041531000050 V041532000025 V041532000040 V041532000050 V041551000025 V041551000040 V041551000050 V041552000025 V041552000040 V041552000050 V041541000020 V041541000025 V041541000030 V041541000035 V041541000040 V041541000045 V041541000050	☐ 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-	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
GUTTAFUSION PINK OBTURATOR 55; 6 PCS GUTTAFUSION PINK OBTURATOR 20; 30 PCS GUTTAFUSION PINK OBTURATOR 25; 30 PCS GUTTAFUSION PINK OBTURATOR 30; 30 PCS GUTTAFUSION PINK OBTURATOR 35; 30 PCS GUTTAFUSION PINK OBTURATOR 40; 30 PCS GUTTAFUSION OBTURATORS, 20-30; 4PCS	V041541000055 V041542000020 V041542000025 V041542000030 V041542000035 V041542000040 V040005000508	made-device		
++E22510037DK Device name and article number: GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS, 6PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS GUTTAMASTER, OBTURATORS,20PCS	 V040505025020 V040505025025 V040505025030 V040505025035 V040505025040 V040505025045 V040505025050 V040505025060 V040506025020 V040506025025 V040506025030 V040506025035 V040506025040 V040506025045 V040506025520	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
++E22510026DE Device name and article number: EDDY	 V041441000000	☐ 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	☒ N/A	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123

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
	☐ Class III implantable custom-made-device		
++E22510021D4 Device name and article number: 2Seal V041020 2Seal easymiX syringe V041025000001 2Seal easymiX tips V041025000002	☐ 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	☒ Certification as follows: G1 015409 0035 REV. 00; NB0123
++E22510002CY Device name and article number: HEDSTROEMFILES, CC+, STERILE V040373021008 HEDSTROEMFILES, CC+, STERILE V040373021010 HEDSTROEMFILES, CC+, STERILE V040373021015 HEDSTROEMFILES, CC+, STERILE V040373021020 HEDSTROEMFILES, CC+, STERILE V040373021025 HEDSTROEMFILES, CC+, STERILE V040373021030 HEDSTROEMFILES, CC+, STERILE V040373021035 HEDSTROEMFILES, CC+, STERILE V040373021040 HEDSTROEMFILES, CC+, STERILE V040373021045 HEDSTROEMFILES, CC+, STERILE V040373021050 HEDSTROEMFILES, CC+, STERILE V040373021055 HEDSTROEMFILES, CC+, STERILE V040373021060 HEDSTROEMFILES, CC+, STERILE V040373021070 HEDSTROEMFILES, CC+, STERILE V040373021080 HEDSTROEMFILES, CC-CORD, STERILE V040373021090 HEDSTROEMFILES, CC-CORD, STERILE V040373021100 HEDSTROEMFILES, CC-CORD, STERILE V040373021110 HEDSTROEMFILES, CC+, STERILE V040373021220	☐ 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-	☒ N/A	☒ Certification as follows: G2S 015409 0027 REV. 00; NB0123

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
HEDSTROEMFILES, CC+, STERILE	V040373021230	made-device		
HEDSTROEMFILES, CC+, STERILE	V040373021240			
HEDSTROEMFILES, CC-CORD, STERILE	V040373021250			
HEDSTROEMFILES, CC+, STERILE	V040373025008			
HEDSTROEMFILES, CC+, STERILE	V040373025010			
HEDSTROEMFILES, CC+, STERILE	V040373025015			
HEDSTROEMFILES, CC+, STERILE	V040373025020			
HEDSTROEMFILES, CC+, STERILE	V040373025025			
HEDSTROEMFILES, CC+, STERILE	V040373025030			
HEDSTROEMFILES, CC+, STERILE	V040373025035			
HEDSTROEMFILES, CC+, STERILE	V040373025040			
HEDSTROEMFILES, CC+, STERILE	V040373025045			
HEDSTROEMFILES, CC+, STERILE	V040373025050			
HEDSTROEMFILES, CC+, STERILE	V040373025055			
HEDSTROEMFILES, CC+, STERILE	V040373025060			
HEDSTROEMFILES, CC+, STERILE	V040373025070			
HEDSTROEMFILES, CC+, STERILE	V040373025080			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025090			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025100			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025110			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025120			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025130			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025140			
HEDSTROEMFILES, CC+, STERILE	V040373025220			
HEDSTROEMFILES, CC+, STERILE	V040373025230			
HEDSTROEMFILES, CC+, STERILE	V040373025240			
HEDSTROEMFILES, CC-CORD, STERILE	V040373025260			
HEDSTROEMFILES, CC+, STERILE	V040373028008			
HEDSTROEMFILES, CC+, STERILE	V040373028010			
HEDSTROEMFILES, CC+, STERILE	V040373028220			
HEDSTROEMFILES, CC+, STERILE	V040373031008			
HEDSTROEMFILES, CC+, STERILE	V040373031010			
HEDSTROEMFILES, CC+, STERILE	V040373031015			
HEDSTROEMFILES, CC+, STERILE	V040373031020			
HEDSTROEMFILES, CC+, STERILE	V040373031025			
HEDSTROEMFILES, CC+, STERILE	V040373031030			
HEDSTROEMFILES, CC+, STERILE	V040373031035			
HEDSTROEMFILES, CC+, STERILE	V040373031040			
HEDSTROEMFILES, CC+, STERILE	V040373031045			
HEDSTROEMFILES, CC+, STERILE	V040373031050			
HEDSTROEMFILES, CC+, STERILE	V040373031055			
HEDSTROEMFILES, CC+, STERILE	V040373031060			
HEDSTROEMFILES, CC+, STERILE	V040373031070			
HEDSTROEMFILES, CC+, STERILE	V040373031080			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031090			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031100			

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
HEDSTROEMFILES, CC-CORD, STERILE	V040373031110			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031120			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031130			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031140			
HEDSTROEMFILES, CC+, STERILE	V040373031220			
HEDSTROEMFILES, CC+, STERILE	V040373031230			
HEDSTROEMFILES, CC+, STERILE	V040373031240			
HEDSTROEMFILES, CC-CORD, STERILE	V040373031260			
++E22510010CX Device name and article number:		☐ 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	☒ Certification as follows: G2S 015409 0027 REV. 00; NB0123
K-REAMERS, CC+, STERILE	V040353021006			
K-REAMERS, CC+, STERILE	V040353021008			
K-REAMERS, CC+, STERILE	V040353021010			
K-REAMERS, CC+, STERILE	V040353021015			
K-REAMERS, CC+, STERILE	V040353021020			
K-REAMERS, CC+, STERILE	V040353021025			
K-REAMERS, CC+, STERILE	V040353021030			
K-REAMERS, CC+, STERILE	V040353021035			
K-REAMERS, CC+, STERILE	V040353021040			
K-REAMERS, CC+, STERILE	V040353021045			
K-REAMERS, CC+, STERILE	V040353021050			
K-REAMERS, CC+, STERILE	V040353021055			
K-REAMERS, CC+, STERILE	V040353021060			
K-REAMERS, CC+, STERILE	V040353021070			
K-REAMERS, CC+, STERILE	V040353021080			
K-REAMERS, CC-CORD, STERILE	V040353021090			
K-REAMERS, CC-CORD, STERILE	V040353021100			
K-REAMERS, CC-CORD, STERILE	V040353021110			
K-REAMERS, CC+, STERILE	V040353021210			
K-REAMERS, CC+, STERILE	V040353021230			
K-REAMERS, CC+, STERILE	V040353021240			
K-REAMERS, CC-CORD, STERILE	V040353021250			
K-REAMERS, CC+, STERILE	V040353025006			
K-REAMERS, CC+, STERILE	V040353025008			
K-REAMERS, CC+, STERILE	V040353025010			
K-REAMERS, CC+, STERILE	V040353025015			
K-REAMERS, CC+, STERILE	V040353025020			
K-REAMERS, CC+, STERILE	V040353025025			
K-REAMERS, CC+, STERILE	V040353025030			
K-REAMERS, CC+, STERILE	V040353025035			
K-REAMERS, CC+, STERILE	V040353025040			
K-REAMERS, CC+, STERILE	V040353025045			
K-REAMERS, CC+, STERILE	V040353025050			
K-REAMERS, CC+, STERILE	V040353025055			
K-REAMERS, CC+, STERILE	V040353025060			
K-REAMERS, CC+, STERILE	V040353025070			

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
K-REAMERS, CC+, STERILE	V040353025080			
K-REAMERS, CC-CORD, STERILE	V040353025090			
K-REAMERS, CC-CORD, STERILE	V040353025100			
K-REAMERS, CC-CORD, STERILE	V040353025110			
K-REAMERS, CC-CORD, STERILE	V040353025120			
K-REAMERS, CC-CORD, STERILE	V040353025130			
K-REAMERS, CC-CORD, STERILE	V040353025140			
K-REAMERS, CC+, STERILE	V040353025210			
K-REAMERS, CC+, STERILE	V040353025230			
K-REAMERS, CC+, STERILE	V040353025240			
K-REAMERS, CC-CORD, STERILE	V040353025260			
K-REAMERS, CC+, STERILE	V040353028006			
K-REAMERS, CC+, STERILE	V040353028008			
K-REAMERS, CC+, STERILE	V040353028010			
K-REAMERS, CC+, STERILE	V040353028210			
K-REAMERS, CC+, STERILE	V040353031006			
K-REAMERS, CC+, STERILE	V040353031008			
K-REAMERS, CC+, STERILE	V040353031010			
K-REAMERS, CC+, STERILE	V040353031015			
K-REAMERS, CC+, STERILE	V040353031020			
K-REAMERS, CC+, STERILE	V040353031025			
K-REAMERS, CC+, STERILE	V040353031030			
K-REAMERS, CC+, STERILE	V040353031035			
K-REAMERS, CC+, STERILE	V040353031040			
K-REAMERS, CC+, STERILE	V040353031045			
K-REAMERS, CC+, STERILE	V040353031050			
K-REAMERS, CC+, STERILE	V040353031055			
K-REAMERS, CC+, STERILE	V040353031060			
K-REAMERS, CC+, STERILE	V040353031070			
K-REAMERS, CC+, STERILE	V040353031080			
K-REAMERS, CC-CORD, STERILE	V040353031090			
K-REAMERS, CC-CORD, STERILE	V040353031100			
K-REAMERS, CC-CORD, STERILE	V040353031110			
K-REAMERS, CC-CORD, STERILE	V040353031120			
K-REAMERS, CC-CORD, STERILE	V040353031130			
K-REAMERS, CC-CORD, STERILE	V040353031140			
K-REAMERS, CC+, STERILE	V040353031210			
K-REAMERS, CC+, STERILE	V040353031230			
K-REAMERS, CC+, STERILE	V040353031240			
K-REAMERS, CC-CORD, STERILE	V040353031260			
++E22510006D8 Device name and article number:		☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G2S 015409
K-FILES, CC+, STERILE	V040363021006			
K-FILES, CC+, STERILE	V040363021008			
K-FILES, CC+, STERILE	V040363021010			
K-FILES, CC+, STERILE	V040363021012			

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
K-FILES, CC+, STERILE	V040363021015	☐ 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		0027 REV. 00; NB0123
K-FILES, CC+, STERILE	V040363021017			
K-FILES, CC+, STERILE	V040363021020			
K-FILES, CC+, STERILE	V040363021025			
K-FILES, CC+, STERILE	V040363021030			
K-FILES, CC+, STERILE	V040363021035			
K-FILES, CC+, STERILE	V040363021040			
K-FILES, CC+, STERILE	V040363021045			
K-FILES, CC+, STERILE	V040363021050			
K-FILES, CC+, STERILE	V040363021055			
K-FILES, CC+, STERILE	V040363021060			
K-FILES, CC+, STERILE	V040363021070			
K-FILES, CC+, STERILE	V040363021080			
K-FILES, CC-CORD, STERILE	V040363021090			
K-FILES, CC-CORD, STERILE	V040363021100			
K-FILES, CC-CORD, STERILE	V040363021110			
K-FILES, CC+, STERILE	V040363021210			
K-FILES, CC+, STERILE	V040363021230			
K-FILES, CC+, STERILE	V040363021240			
K-FILES, CC-CORD, STERILE	V040363021250			
K-FILES, CC+, STERILE	V040363025006			
K-FILES, CC+, STERILE	V040363025008			
K-FILES, CC+, STERILE	V040363025010			
K-FILES, CC+, STERILE	V040363025012			
K-FILES, CC+, STERILE	V040363025015			
K-FILES, CC+, STERILE	V040363025017			
K-FILES, CC+, STERILE	V040363025020			
K-FILES, CC+, STERILE	V040363025025			
K-FILES, CC+, STERILE	V040363025030			
K-FILES, CC+, STERILE	V040363025035			
K-FILES, CC+, STERILE	V040363025040			
K-FILES, CC+, STERILE	V040363025045			
K-FILES, CC+, STERILE	V040363025050			
K-FILES, CC+, STERILE	V040363025055			
K-FILES, CC+, STERILE	V040363025060			
K-FILES, CC+, STERILE	V040363025070			
K-FILES, CC+, STERILE	V040363025080			
K-FILES, CC-CORD, STERILE	V040363025090			
K-FILES, CC-CORD, STERILE	V040363025100			
K-FILES, CC-CORD, STERILE	V040363025110			
K-FILES, CC-CORD, STERILE	V040363025120			
K-FILES, CC-CORD, STERILE	V040363025130			
K-FILES, CC-CORD, STERILE	V040363025140			
K-FILES, CC+, STERILE	V040363025210			
K-FILES, CC+, STERILE	V040363025230			
K-FILES, CC+, STERILE	V040363025240			

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
K-FILES, CC-CORD, STERILE	V040363025260			
K-FILES, CC+, STERILE	V040363028006			
K-FILES, CC+, STERILE	V040363028008			
K-FILES, CC+, STERILE	V040363028010			
K-FILES, CC+, STERILE	V040363028210			
K-FILES, CC+, STERILE	V040363031006			
K-FILES, CC+, STERILE	V040363031008			
K-FILES, CC+, STERILE	V040363031010			
K-FILES, CC+, STERILE	V040363031015			
K-FILES, CC+, STERILE	V040363031020			
K-FILES, CC+, STERILE	V040363031025			
K-FILES, CC+, STERILE	V040363031030			
K-FILES, CC+, STERILE	V040363031035			
K-FILES, CC+, STERILE	V040363031040			
K-FILES, CC+, STERILE	V040363031045			
K-FILES, CC+, STERILE	V040363031050			
K-FILES, CC+, STERILE	V040363031055			
K-FILES, CC+, STERILE	V040363031060			
K-FILES, CC+, STERILE	V040363031070			
K-FILES, CC+, STERILE	V040363031080			
K-FILES, CC-CORD, STERILE	V040363031090			
K-FILES, CC-CORD, STERILE	V040363031100			
K-FILES, CC-CORD, STERILE	V040363031110			
K-FILES, CC-CORD, STERILE	V040363031120			
K-FILES, CC-CORD, STERILE	V040363031130			
K-FILES, CC-CORD, STERILE	V040363031140			
K-FILES, CC+, STERILE	V040363031210			
K-FILES, CC+, STERILE	V040363031230			
K-FILES, CC+, STERILE	V040363031240			
K-FILES, CC-CORD, STERILE	V040363031260			
++E22510001CW Device name and article number:		☐ 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	☒ N/A	☒ Certification as follows: G2S 015409 0027 REV. 00; NB0123
C-PILOT FILES, CC+, STERILE	V040368019006			
C-PILOT FILES, CC+, STERILE	V040368019008			
C-PILOT FILES, CC+, STERILE	V040368019010			
C-PILOT FILES, CC+, STERILE	V040368019012			
C-PILOT FILES, CC+, STERILE	V040368019015			
C-PILOT FILES, CC+, STERILE	V040368019210			
C-PILOT FILES, CC+, STERILE	V040368021006			
C-PILOT FILES, CC+, STERILE	V040368021008			
C-PILOT FILES, CC+, STERILE	V040368021010			
C-PILOT FILES, CC+, STERILE	V040368021012			
C-PILOT FILES, CC+, STERILE	V040368021015			
C-PILOT FILES, CC+, STERILE	V040368021210			
C-PILOT FILES, CC+, STERILE	V040368025006			
C-PILOT FILES, CC+, STERILE	V040368025008			

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
C-PILOT FILES, CC+, STERILE C-PILOT FILES, CC+, STERILE C-PILOT FILES, CC+, STERILE C-PILOT FILES, CC+, STERILE	V040368025010 V040368025012 V040368025015 V040368025210	measuring function ☐ Class III implantable custom-made-device		

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
++E22510007DA Device name and article number: K-FILES, CC+ V010063021006 K-FILES, CC+ V010063021008 K-FILES, CC+ V010063021010 K-FILES, CC+ V010063021015 K-FILES, CC+ V010063021020 K-FILES, CC+ V010063021025 K-FILES, CC+ V010063021030 K-FILES, CC+ V010063021035 K-FILES, CC+ V010063021040 K-FILES, CC+ V010063021230 K-FILES, CC+ V010063021240 K-FILES, CC+ V010063025006 K-FILES, CC+ V010063025008 K-FILES, CC+ V010063025010 K-FILES, CC+ V010063025015 K-FILES, CC+ V010063025020 K-FILES, CC+ V010063025025 K-FILES, CC+ V010063025030 K-FILES, CC+ V010063025035 K-FILES, CC+ V010063025040 K-FILES, CC+ V010063025210 K-FILES, CC+ V010063025230 K-FILES, CC+ V010063025240 K-FILES, CC+ V010063031006 K-FILES, CC+ V010063031008 K-FILES, CC+ V010063031010 K-FILES, CC+ V010063031015 K-FILES, CC+ V010063031020 K-FILES, CC+ V010063031025 K-FILES, CC+ V010063031030 K-FILES, CC+ V010063031035 K-FILES, CC+ V010063031040 K-FILES, CC+ V010063031230 K-FILES, CC+ V010063031240 K-FILES, CC+ V020063021006 K-FILES, CC+ V020063021008 K-FILES, CC+ V020063021010 K-FILES, CC+ V020063021015 K-FILES, CC+ V020063021020 K-FILES, CC+ V020063021025	☐ 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 I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ 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 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
K-FILES, CC+	V020063021030			
K-FILES, CC+	V020063021035			
K-FILES, CC+	V020063021040			
K-FILES, CC+	V020063021045			
K-FILES, CC+	V020063021050			
K-FILES, CC+	V020063021055			
K-FILES, CC+	V020063021060			
K-FILES, CC+	V020063021070			
K-FILES, CC+	V020063021080			
K-FILES, CC+	V020063021230			
K-FILES, CC+	V020063021240			
K-FILES, CC+	V020063025006			
K-FILES, CC+	V020063025008			
K-FILES, CC+	V020063025010			
K-FILES, CC+	V020063025012			
K-FILES, CC+	V020063025015			
K-FILES, CC+	V020063025017			
K-FILES, CC+	V020063025020			
K-FILES, CC+	V020063025025			
K-FILES, CC+	V020063025030			
K-FILES, CC+	V020063025035			
K-FILES, CC+	V020063025040			
K-FILES, CC+	V020063025045			
K-FILES, CC+	V020063025050			
K-FILES, CC+	V020063025055			
K-FILES, CC+	V020063025060			
K-FILES, CC+	V020063025070			
K-FILES, CC+	V020063025080			
K-FILES, CC+	V020063025230			
K-FILES, CC+	V020063025240			
K-FILES, CC+	V020063031006			
K-FILES, CC+	V020063031008			
K-FILES, CC+	V020063031010			
K-FILES, CC+	V020063031015			
K-FILES, CC+	V020063031020			
K-FILES, CC+	V020063031025			
K-FILES, CC+	V020063031030			
K-FILES, CC+	V020063031035			
K-FILES, CC+	V020063031040			
K-FILES, CC+	V020063031230			
K-FILES, CC+	V020063031240			
K-FILES, CC+	V030063021006			
K-FILES, CC+	V030063021008			
K-FILES, CC+	V030063021010			
K-FILES, CC+	V030063021015			
K-FILES, CC+	V030063021020			

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
K-FILES, CC+	V030063021025			
K-FILES, CC+	V030063021030			
K-FILES, CC+	V030063021035			
K-FILES, CC+	V030063021040			
K-FILES, CC+	V030063021045			
K-FILES, CC+	V030063021050			
K-FILES, CC+	V030063021055			
K-FILES, CC+	V030063021060			
K-FILES, CC+	V030063021070			
K-FILES, CC+	V030063021080			
K-FILES, CC+	V030063021210			
K-FILES, CC+	V030063021230			
K-FILES, CC+	V030063021240			
K-FILES, CC+	V030063025006			
K-FILES, CC+	V030063025008			
K-FILES, CC+	V030063025010			
K-FILES, CC+	V030063025015			
K-FILES, CC+	V030063025020			
K-FILES, CC+	V030063025025			
K-FILES, CC+	V030063025030			
K-FILES, CC+	V030063025035			
K-FILES, CC+	V030063025040			
K-FILES, CC+	V030063025045			
K-FILES, CC+	V030063025050			
K-FILES, CC+	V030063025055			
K-FILES, CC+	V030063025060			
K-FILES, CC+	V030063025070			
K-FILES, CC+	V030063025080			
K-FILES, CC+	V030063025210			
K-FILES, CC+	V030063025230			
K-FILES, CC+	V030063025240			
K-FILES, CC+	V030063031006			
K-FILES, CC+	V030063031008			
K-FILES, CC+	V030063031010			
K-FILES, CC+	V030063031015			
K-FILES, CC+	V030063031020			
K-FILES, CC+	V030063031025			
K-FILES, CC+	V030063031030			
K-FILES, CC+	V030063031035			
K-FILES, CC+	V030063031040			
K-FILES, CC+	V030063031045			
K-FILES, CC+	V030063031050			
K-FILES, CC+	V030063031055			
K-FILES, CC+	V030063031060			
K-FILES, CC+	V030063031070			
K-FILES, CC+	V030063031080			

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
K-FILES, CC+	V030063031210				
K-FILES, CC+	V030063031230				
K-FILES, CC+	V030063031240				
KENDO K-FILE	V200706021006	V201706021006			
KENDO K-FILE	V200706021008	V201706021008			
KENDO K-FILE	V200706021010	V201706021010			
KENDO K-FILE	V200706021015	V201706021015			
KENDO K-FILE	V200706021020	V201706021020			
KENDO K-FILE	V200706021025	V201706021025			
KENDO K-FILE	V200706021030	V201706021030			
KENDO K-FILE	V200706021035	V201706021035			
KENDO K-FILE	V200706021040	V201706021040			
KENDO K-FILE	V200706021210	V201706021210			
KENDO K-FILE	V200706021230	V201706021230			
KENDO K-FILE	V200706021240	V201706021240			
KENDO K-FILE	V200706025006	V201706025006			
KENDO K-FILE	V200706025008	V201706025008			
KENDO K-FILE	V200706025010	V201706025010			
KENDO K-FILE	V200706025015	V201706025015			
KENDO K-FILE	V200706025020	V201706025020			
KENDO K-FILE	V200706025025	V201706025025			
KENDO K-FILE	V200706025030	V201706025030			
KENDO K-FILE	V200706025035	V201706025035			
KENDO K-FILE	V200706025040	V201706025040			
KENDO K-FILE	V200706025210	V201706025210			
KENDO K-FILE	V200706025230	V201706025230			
KENDO K-FILE	V200706025240	V201706025240			
KENDO K-FILE	V200706031006	V201706031006			
KENDO K-FILE	V200706031008	V201706031008			
KENDO K-FILE	V200706031010	V201706031010			
KENDO K-FILE	V200706031015	V201706031015			
KENDO K-FILE	V200706031020	V201706031020			
KENDO K-FILE	V200706031025	V201706031025			
KENDO K-FILE	V200706031030	V201706031030			
KENDO K-FILE	V200706031035	V201706031035			
KENDO K-FILE	V200706031040	V201706031040			
KENDO K-FILE	V200706031210	V201706031210			
KENDO K-FILE	V200706031230	V201706031230			
KENDO K-FILE	V200706031240	V201706031240			
PRO-ENDO K-FILE	V200606021035				
PRO-ENDO K-FILE	V200606021040				
PRO-ENDO K-FILE	V200606021045				
PRO-ENDO K-FILE	V200606021050				
PRO-ENDO K-FILE	V200606021055				
PRO-ENDO K-FILE	V200606021060				
PRO-ENDO K-FILE	V200606021070				

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
PRO-ENDO K-FILE V200606021080 PRO-ENDO K-FILE V200606021230 PRO-ENDO K-FILE V200606021240 PRO-ENDO K-FILE V200606025035 PRO-ENDO K-FILE V200606025040 PRO-ENDO K-FILE V200606025045 PRO-ENDO K-FILE V200606025050 PRO-ENDO K-FILE V200606025055 PRO-ENDO K-FILE V200606025060 PRO-ENDO K-FILE V200606025070 PRO-ENDO K-FILE V200606025080 PRO-ENDO K-FILE V200606025210 PRO-ENDO K-FILE V200606025225 PRO-ENDO K-FILE V200606025230 PRO-ENDO K-FILE V200606025240 PRO-ENDO K-FILE V200606028035 PRO-ENDO K-FILE V200606028040 PRO-ENDO K-FILE V200606028045 PRO-ENDO K-FILE V200606028050 PRO-ENDO K-FILE V200606028055 PRO-ENDO K-FILE V200606028060 PRO-ENDO K-FILE V200606028070 PRO-ENDO K-FILE V200606028080 PRO-ENDO K-FILE V200606028225 PRO-ENDO K-FILE V200606028230 PRO-ENDO K-FILE V200606028240 PRO-ENDO K-FILE V200606031035 PRO-ENDO K-FILE V200606031040 PRO-ENDO K-FILE V200606031045 PRO-ENDO K-FILE V200606031050 PRO-ENDO K-FILE V200606031055 PRO-ENDO K-FILE V200606031060 PRO-ENDO K-FILE V200606031070 PRO-ENDO K-FILE V200606031080 PRO-ENDO K-FILE V200606031210 PRO-ENDO K-FILE V200606031225 PRO-ENDO K-FILE V200606031230 PRO-ENDO K-FILE V200606031240			
++E22510011CZ Device name and article number: K-REAMER, CC+ V010053021006 K-REAMER, CC+ V010053021008 K-REAMER, CC+ V010053021010 K-REAMER, CC+ V010053021015 K-REAMER, CC+ V010053021020	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb	☒ 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 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
K-REAMER, CC+	V010053021025	implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
K-REAMER, CC+	V010053021030			
K-REAMER, CC+	V010053021035			
K-REAMER, CC+	V010053021040			
K-REAMER, CC+	V010053021230			
K-REAMER, CC+	V010053021240			
K-REAMER, CC+	V010053025006			
K-REAMER, CC+	V010053025008			
K-REAMER, CC+	V010053025010			
K-REAMER, CC+	V010053025015			
K-REAMER, CC+	V010053025020			
K-REAMER, CC+	V010053025025			
K-REAMER, CC+	V010053025030			
K-REAMER, CC+	V010053025035			
K-REAMER, CC+	V010053025040			
K-REAMER, CC+	V010053025210			
K-REAMER, CC+	V010053025230			
K-REAMER, CC+	V010053025240			
K-REAMER, CC+	V020053021006			
K-REAMER, CC+	V020053021008			
K-REAMER, CC+	V020053021010			
K-REAMER, CC+	V020053021015			
K-REAMER, CC+	V020053021020			
K-REAMER, CC+	V020053021025			
K-REAMER, CC+	V020053021030			
K-REAMER, CC+	V020053021035			
K-REAMER, CC+	V020053021040			
K-REAMER, CC+	V020053021230			
K-REAMER, CC+	V020053021240			
K-REAMER, CC+	V020053025006			
K-REAMER, CC+	V020053025008			
K-REAMER, CC+	V020053025010			
K-REAMER, CC+	V020053025015			
K-REAMER, CC+	V020053025020			
K-REAMER, CC+	V020053025025			
K-REAMER, CC+	V020053025030			
K-REAMER, CC+	V020053025035			
K-REAMER, CC+	V020053025040			
K-REAMER, CC+	V020053025210			
K-REAMER, CC+	V020053025230			
K-REAMER, CC+	V020053025240			
K-REAMER, CC+	V020053031006			
K-REAMER, CC+	V020053031008			
K-REAMER, CC+	V020053031010			
K-REAMER, CC+	V020053031015			
K-REAMER, CC+	V020053031020			

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
K-REAMER, CC+	V020053031025			
K-REAMER, CC+	V020053031030			
K-REAMER, CC+	V020053031035			
K-REAMER, CC+	V020053031040			
K-REAMER, CC+	V030053021006			
K-REAMER, CC+	V030053021008			
K-REAMER, CC+	V030053021010			
K-REAMER, CC+	V030053021015			
K-REAMER, CC+	V030053021020			
K-REAMER, CC+	V030053021025			
K-REAMER, CC+	V030053021030			
K-REAMER, CC+	V030053021035			
K-REAMER, CC+	V030053021040			
K-REAMER, CC+	V030053021045			
K-REAMER, CC+	V030053021050			
K-REAMER, CC+	V030053021055			
K-REAMER, CC+	V030053021060			
K-REAMER, CC+	V030053021070			
K-REAMER, CC+	V030053021080			
K-REAMER, CC+	V030053021210			
K-REAMER, CC+	V030053021230			
K-REAMER, CC+	V030053021240			
K-REAMER, CC+	V030053025006			
K-REAMER, CC+	V030053025008			
K-REAMER, CC+	V030053025010			
K-REAMER, CC+	V030053025015			
K-REAMER, CC+	V030053025020			
K-REAMER, CC+	V030053025025			
K-REAMER, CC+	V030053025030			
K-REAMER, CC+	V030053025035			
K-REAMER, CC+	V030053025040			
K-REAMER, CC+	V030053025045			
K-REAMER, CC+	V030053025050			
K-REAMER, CC+	V030053025055			
K-REAMER, CC+	V030053025060			
K-REAMER, CC+	V030053025070			
K-REAMER, CC+	V030053025080			
K-REAMER, CC+	V030053025210			
K-REAMER, CC+	V030053025230			
K-REAMER, CC+	V030053025240			
K-REAMER, CC+	V030053031008			
K-REAMER, CC+	V030053031010			
K-REAMER, CC+	V030053031015			
K-REAMER, CC+	V030053031020			
K-REAMER, CC+	V030053031025			
K-REAMER, CC+	V030053031030			

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
K-REAMER, CC+	V030053031035				
K-REAMER, CC+	V030053031040				
K-REAMER, CC+	V030053031045				
K-REAMER, CC+	V030053031050				
K-REAMER, CC+	V030053031055				
K-REAMER, CC+	V030053031060				
K-REAMER, CC+	V030053031070				
K-REAMER, CC+	V030053031080				
K-REAMER, CC+	V030053031230				
K-REAMER, CC+	V030053031240				
KENDO K-REAMER	V200705021006	V201705021006			
KENDO K-REAMER	V200705021008	V201705021008			
KENDO K-REAMER	V200705021010	V201705021010			
KENDO K-REAMER	V200705021015	V201705021015			
KENDO K-REAMER	V200705021020	V201705021020			
KENDO K-REAMER	V200705021025	V201705021025			
KENDO K-REAMER	V200705021030	V201705021030			
KENDO K-REAMER	V200705021035	V201705021035			
KENDO K-REAMER	V200705021040	V201705021040			
KENDO K-REAMER	V200705021230	V201705021230			
KENDO K-REAMER	V200705021240	V201705021240			
KENDO K-REAMER	V200705025006	V201705025006			
KENDO K-REAMER	V200705025008	V201705025008			
KENDO K-REAMER	V200705025010	V201705025010			
KENDO K-REAMER	V200705025015	V201705025015			
KENDO K-REAMER	V200705025020	V201705025020			
KENDO K-REAMER	V200705025025	V201705025025			
KENDO K-REAMER	V200705025030	V201705025030			
KENDO K-REAMER	V200705025035	V201705025035			
KENDO K-REAMER	V200705025040	V201705025040			
KENDO K-REAMER	V200705025230	V201705025230			
KENDO K-REAMER	V200705025240	V201705025240			
KENDO K-REAMER	V200705031006	V201705031006			
KENDO K-REAMER	V200705031008	V201705031008			
KENDO K-REAMER	V200705031010	V201705031010			
KENDO K-REAMER	V200705031015	V201705031015			
KENDO K-REAMER	V200705031020	V201705031020			
KENDO K-REAMER	V200705031025	V201705031025			
KENDO K-REAMER	V200705031030	V201705031030			
KENDO K-REAMER	V200705031035	V201705031035			
KENDO K-REAMER	V200705031040	V201705031040			
KENDO K-REAMER	V200705031230	V201705031230			
KENDO K-REAMER	V200705031240	V201705031240			
PRO-ENDO K-REAMER	V200605021006				
PRO-ENDO K-REAMER	V200605021008				

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
PRO-ENDO K-REAMER	V200605021010			
PRO-ENDO K-REAMER	V200605021015			
PRO-ENDO K-REAMER	V200605021020			
PRO-ENDO K-REAMER	V200605021025			
PRO-ENDO K-REAMER	V200605021030			
PRO-ENDO K-REAMER	V200605021035			
PRO-ENDO K-REAMER	V200605021040			
PRO-ENDO K-REAMER	V200605021045			
PRO-ENDO K-REAMER	V200605021050			
PRO-ENDO K-REAMER	V200605021055			
PRO-ENDO K-REAMER	V200605021060			
PRO-ENDO K-REAMER	V200605021070			
PRO-ENDO K-REAMER	V200605021080			
PRO-ENDO K-REAMER	V200605021230			
PRO-ENDO K-REAMER	V200605021240			
PRO-ENDO K-REAMER	V200605025006			
PRO-ENDO K-REAMER	V200605025008			
PRO-ENDO K-REAMER	V200605025010			
PRO-ENDO K-REAMER	V200605025015			
PRO-ENDO K-REAMER	V200605025020			
PRO-ENDO K-REAMER	V200605025025			
PRO-ENDO K-REAMER	V200605025030			
PRO-ENDO K-REAMER	V200605025035			
PRO-ENDO K-REAMER	V200605025040			
PRO-ENDO K-REAMER	V200605025045			
PRO-ENDO K-REAMER	V200605025050			
PRO-ENDO K-REAMER	V200605025055			
PRO-ENDO K-REAMER	V200605025060			

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
PRO-ENDO K-REAMER	V200605025070			
PRO-ENDO K-REAMER	V200605025080			
PRO-ENDO K-REAMER	V200605025210			
PRO-ENDO K-REAMER	V200605025230			
PRO-ENDO K-REAMER	V200605025240			
PRO-ENDO K-REAMER	V200605028006			
PRO-ENDO K-REAMER	V200605028008			
PRO-ENDO K-REAMER	V200605028010			
PRO-ENDO K-REAMER	V200605028015			
PRO-ENDO K-REAMER	V200605028020			
PRO-ENDO K-REAMER	V200605028025			
PRO-ENDO K-REAMER	V200605028030			
PRO-ENDO K-REAMER	V200605028035			
PRO-ENDO K-REAMER	V200605028040			
PRO-ENDO K-REAMER	V200605028045			
PRO-ENDO K-REAMER	V200605028050			
PRO-ENDO K-REAMER	V200605028055			
PRO-ENDO K-REAMER	V200605028060			
PRO-ENDO K-REAMER	V200605028070			
PRO-ENDO K-REAMER	V200605028080			
PRO-ENDO K-REAMER	V200605028230			
PRO-ENDO K-REAMER	V200605028240			
PRO-ENDO K-REAMER	V200605031006			
PRO-ENDO K-REAMER	V200605031008			
PRO-ENDO K-REAMER	V200605031010			
PRO-ENDO K-REAMER	V200605031015			
PRO-ENDO K-REAMER	V200605031020			
PRO-ENDO K-REAMER	V200605031025			

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
PRO-ENDO K-REAMER V200605031030 PRO-ENDO K-REAMER V200605031035 PRO-ENDO K-REAMER V200605031040 PRO-ENDO K-REAMER V200605031045 PRO-ENDO K-REAMER V200605031050 PRO-ENDO K-REAMER V200605031055 PRO-ENDO K-REAMER V200605031060 PRO-ENDO K-REAMER V200605031070 PRO-ENDO K-REAMER V200605031080 PRO-ENDO K-REAMER V200605031230 PRO-ENDO K-REAMER V200605031240			
++E22510003D2 Device name and article number: HEDSTROEM-FILES, CC+ V010073021008 HEDSTROEM-FILES, CC+ V010073021010 HEDSTROEM-FILES, CC+ V010073021015 HEDSTROEM-FILES, CC+ V010073021020 HEDSTROEM-FILES, CC+ V010073021025 HEDSTROEM-FILES, CC+ V010073021030 HEDSTROEM-FILES, CC+ V010073021035 HEDSTROEM-FILES, CC+ V010073021040 HEDSTROEM-FILES, CC+ V010073021230 HEDSTROEM-FILES, CC+ V010073021240 HEDSTROEM-FILES, CC+ V010073025008 HEDSTROEM-FILES, CC+ V010073025010 HEDSTROEM-FILES, CC+ V010073025015 HEDSTROEM-FILES, CC+ V010073025020 HEDSTROEM-FILES, CC+ V010073025025 HEDSTROEM-FILES, CC+ V010073025030 HEDSTROEM-FILES, CC+ V010073025035 HEDSTROEM-FILES, CC+ V010073025040 HEDSTROEM-FILES, CC+ V010073025230 HEDSTROEM-FILES, CC+ V010073025240 HEDSTROEM-FILES, CC+ V010073031230 HEDSTROEM-FILES, CC+ V010073031240 HEDSTROEM-FILES, CC+ V020073021008 HEDSTROEM-FILES, CC+ V020073021010 HEDSTROEM-FILES, CC+ V020073021015	☐ 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 I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ 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 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
HEDSTROEM-FILES, CC+	V020073021020			
HEDSTROEM-FILES, CC+	V020073021025			
HEDSTROEM-FILES, CC+	V020073021030			
HEDSTROEM-FILES, CC+	V020073021035			
HEDSTROEM-FILES, CC+	V020073021040			
HEDSTROEM-FILES, CC+	V020073021230			
HEDSTROEM-FILES, CC+	V020073021240			
HEDSTROEM-FILES, CC+	V020073025008			
HEDSTROEM-FILES, CC+	V020073025010			
HEDSTROEM-FILES, CC+	V020073025015			
HEDSTROEM-FILES, CC+	V020073025020			
HEDSTROEM-FILES, CC+	V020073025025			
HEDSTROEM-FILES, CC+	V020073025030			
HEDSTROEM-FILES, CC+	V020073025035			
HEDSTROEM-FILES, CC+	V020073025040			
HEDSTROEM-FILES, CC+	V020073025230			
HEDSTROEM-FILES, CC+	V020073025240			
HEDSTROEM-FILES, CC+	V020073031008			
HEDSTROEM-FILES, CC+	V020073031010			
HEDSTROEM-FILES, CC+	V020073031015			
HEDSTROEM-FILES, CC+	V020073031020			
HEDSTROEM-FILES, CC+	V020073031025			
HEDSTROEM-FILES, CC+	V020073031030			
HEDSTROEM-FILES, CC+	V020073031035			
HEDSTROEM-FILES, CC+	V020073031040			
HEDSTROEM-FILES, CC+	V020073031230			
HEDSTROEM-FILES, CC+	V020073031240			
HEDSTROEM-FILES, CC+	V030073021008			
HEDSTROEM-FILES, CC+	V030073021010			
HEDSTROEM-FILES, CC+	V030073021015			
HEDSTROEM-FILES, CC+	V030073021020			
HEDSTROEM-FILES, CC+	V030073021025			
HEDSTROEM-FILES, CC+	V030073021030			
HEDSTROEM-FILES, CC+	V030073021035			
HEDSTROEM-FILES, CC+	V030073021040			
HEDSTROEM-FILES, CC+	V030073021045			
HEDSTROEM-FILES, CC+	V030073021050			
HEDSTROEM-FILES, CC+	V030073021055			
HEDSTROEM-FILES, CC+	V030073021060			
HEDSTROEM-FILES, CC+	V030073021070			
HEDSTROEM-FILES, CC+	V030073021080			
HEDSTROEM-FILES, CC+	V030073021220			
HEDSTROEM-FILES, CC+	V030073021230			
HEDSTROEM-FILES, CC+	V030073021240			
HEDSTROEM-FILES, CC+	V030073025008			
HEDSTROEM-FILES, CC+	V030073025010			

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
HEDSTROEM-FILES, CC+	V030073025015				
HEDSTROEM-FILES, CC+	V030073025020				
HEDSTROEM-FILES, CC+	V030073025025				
HEDSTROEM-FILES, CC+	V030073025030				
HEDSTROEM-FILES, CC+	V030073025035				
HEDSTROEM-FILES, CC+	V030073025040				
HEDSTROEM-FILES, CC+	V030073025045				
HEDSTROEM-FILES, CC+	V030073025050				
HEDSTROEM-FILES, CC+	V030073025055				
HEDSTROEM-FILES, CC+	V030073025060				
HEDSTROEM-FILES, CC+	V030073025070				
HEDSTROEM-FILES, CC+	V030073025080				
HEDSTROEM-FILES, CC+	V030073025220				
HEDSTROEM-FILES, CC+	V030073025230				
HEDSTROEM-FILES, CC+	V030073025240				
HEDSTROEM-FILES, CC+	V030073031008				
HEDSTROEM-FILES, CC+	V030073031010				
HEDSTROEM-FILES, CC+	V030073031015				
HEDSTROEM-FILES, CC+	V030073031020				
HEDSTROEM-FILES, CC+	V030073031025				
HEDSTROEM-FILES, CC+	V030073031030				
HEDSTROEM-FILES, CC+	V030073031035				
HEDSTROEM-FILES, CC+	V030073031040				
HEDSTROEM-FILES, CC+	V030073031045				
HEDSTROEM-FILES, CC+	V030073031050				
HEDSTROEM-FILES, CC+	V030073031055				
HEDSTROEM-FILES, CC+	V030073031060				
HEDSTROEM-FILES, CC+	V030073031220				
HEDSTROEM-FILES, CC+	V030073031230				
HEDSTROEM-FILES, CC+	V030073031240				
KENDO HEDSTROEM FILE	V200707021008	V201707021008			
KENDO HEDSTROEM FILE	V200707021010	V201707021010			
KENDO HEDSTROEM FILE	V200707021015	V201707021015			
KENDO HEDSTROEM FILE	V200707021020	V201707021020			
KENDO HEDSTROEM FILE	V200707021025	V201707021025			
KENDO HEDSTROEM FILE	V200707021030	V201707021030			
KENDO HEDSTROEM FILE	V200707021035	V201707021035			
KENDO HEDSTROEM FILE	V200707021040	V201707021040			
KENDO HEDSTROEM FILE	V200707021220	V201707021220			
KENDO HEDSTROEM FILE	V200707021230	V201707021230			
KENDO HEDSTROEM FILE	V200707021240	V201707021240			
KENDO HEDSTROEM FILE	V200707025008	V201707025008			
KENDO HEDSTROEM FILE	V200707025010	V201707025010			
KENDO HEDSTROEM FILE	V200707025015	V201707025015			
KENDO HEDSTROEM FILE	V200707025020	V201707025020			
KENDO HEDSTROEM FILE	V200707025025	V201707025025			

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
KENDO HEDSTROEM FILE	V200707025030	V201707025030			
KENDO HEDSTROEM FILE	V200707025035	V201707025035			
KENDO HEDSTROEM FILE	V200707025040	V201707025040			
KENDO HEDSTROEM FILE	V200707025220	V201707025220			
KENDO HEDSTROEM FILE	V200707025230	V201707025230			
KENDO HEDSTROEM FILE	V200707025240	V201707025240			
KENDO HEDSTROEM FILE	V200707031008	V201707031008			
KENDO HEDSTROEM FILE	V200707031010	V201707031010			
KENDO HEDSTROEM FILE	V200707031015	V201707031015			
KENDO HEDSTROEM FILE	V200707031020	V201707031020			
KENDO HEDSTROEM FILE	V200707031025	V201707031025			
KENDO HEDSTROEM FILE	V200707031030	V201707031030			
KENDO HEDSTROEM FILE	V200707031035	V201707031035			
KENDO HEDSTROEM FILE	V200707031040	V201707031040			
KENDO HEDSTROEM FILE	V200707031220	V201707031220			
KENDO HEDSTROEM FILE	V200707031230	V201707031230			
KENDO HEDSTROEM FILE	V200707031240	V201707031240			
PRO-ENDO HEDSTROEM FILE	V200607021008				
PRO-ENDO HEDSTROEM FILE	V200607021010				
PRO-ENDO HEDSTROEM FILE	V200607021015				
PRO-ENDO HEDSTROEM FILE	V200607021020				
PRO-ENDO HEDSTROEM FILE	V200607021025				
PRO-ENDO HEDSTROEM FILE	V200607021030				
PRO-ENDO HEDSTROEM FILE	V200607021035				
PRO-ENDO HEDSTROEM FILE	V200607021040				
PRO-ENDO HEDSTROEM FILE	V200607021045				
PRO-ENDO HEDSTROEM FILE	V200607021050				
PRO-ENDO HEDSTROEM FILE	V200607021055				
PRO-ENDO HEDSTROEM FILE	V200607021060				
PRO-ENDO HEDSTROEM FILE	V200607021070				
PRO-ENDO HEDSTROEM FILE	V200607021080				
PRO-ENDO HEDSTROEM FILE	V200607021230				
PRO-ENDO HEDSTROEM FILE	V200607021240				
PRO-ENDO HEDSTROEM FILE	V200607025008				
PRO-ENDO HEDSTROEM FILE	V200607025010				

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
PRO-ENDO HEDSTROEM FILE V200607025015			
PRO-ENDO HEDSTROEM FILE V200607025020			
PRO-ENDO HEDSTROEM FILE V200607025025			
PRO-ENDO HEDSTROEM FILE V200607025030			
PRO-ENDO HEDSTROEM FILE V200607025035			
PRO-ENDO HEDSTROEM FILE V200607025040			
PRO-ENDO HEDSTROEM FILE V200607025045			
PRO-ENDO HEDSTROEM FILE V200607025050			
PRO-ENDO HEDSTROEM FILE V200607025055			
PRO-ENDO HEDSTROEM FILE V200607025060			
PRO-ENDO HEDSTROEM FILE V200607025070			
PRO-ENDO HEDSTROEM FILE V200607025080			
PRO-ENDO HEDSTROEM FILE V200607025220			
PRO-ENDO HEDSTROEM FILE V200607025230			
PRO-ENDO HEDSTROEM FILE V200607025240			
PRO-ENDO HEDSTROEM FILE V200607028008			
PRO-ENDO HEDSTROEM FILE V200607028010			
PRO-ENDO HEDSTROEM FILE V200607028015			
PRO-ENDO HEDSTROEM FILE V200607028020			
PRO-ENDO HEDSTROEM FILE V200607028025			
PRO-ENDO HEDSTROEM FILE V200607028030			
PRO-ENDO HEDSTROEM FILE V200607028035			
PRO-ENDO HEDSTROEM FILE V200607028040			
PRO-ENDO HEDSTROEM FILE V200607028045			
PRO-ENDO HEDSTROEM FILE V200607028050			
PRO-ENDO HEDSTROEM FILE V200607028055			
PRO-ENDO HEDSTROEM FILE V200607028060			
PRO-ENDO HEDSTROEM FILE V200607028070			

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
PRO-ENDO HEDSTROEM FILE V200607028080			
PRO-ENDO HEDSTROEM FILE V200607028230			
PRO-ENDO HEDSTROEM FILE V200607028240			
PRO-ENDO HEDSTROEM FILE V200607031008			
PRO-ENDO HEDSTROEM FILE V200607031010			
PRO-ENDO HEDSTROEM FILE V200607031015			
PRO-ENDO HEDSTROEM FILE V200607031020			
PRO-ENDO HEDSTROEM FILE V200607031025			
PRO-ENDO HEDSTROEM FILE V200607031030			
PRO-ENDO HEDSTROEM FILE V200607031035			
PRO-ENDO HEDSTROEM FILE V200607031040			
PRO-ENDO HEDSTROEM FILE V200607031045			
PRO-ENDO HEDSTROEM FILE V200607031050			
PRO-ENDO HEDSTROEM FILE V200607031055			
PRO-ENDO HEDSTROEM FILE V200607031060			
PRO-ENDO HEDSTROEM FILE V200607031070			
PRO-ENDO HEDSTROEM FILE V200607031080			
PRO-ENDO HEDSTROEM FILE V200607031230			
PRO-ENDO HEDSTROEM FILE V200607031240			

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
++E22510025DC Device name and article number: PRO-ENDO K-FILE V200606021006 PRO-ENDO K-FILE V200606021008 PRO-ENDO K-FILE V200606021010 PRO-ENDO K-FILE V200606021012 PRO-ENDO K-FILE V200606021015 PRO-ENDO K-FILE V200606021017 PRO-ENDO K-FILE V200606021020 PRO-ENDO K-FILE V200606021025 PRO-ENDO K-FILE V200606021030 PRO-ENDO K-FILE V200606021210 PRO-ENDO K-FILE V200606021225 PRO-ENDO K-FILE V200606025006 PRO-ENDO K-FILE V200606025008 PRO-ENDO K-FILE V200606025010 PRO-ENDO K-FILE V200606025012 PRO-ENDO K-FILE V200606025015 PRO-ENDO K-FILE V200606025017 PRO-ENDO K-FILE V200606025020 PRO-ENDO K-FILE V200606025025 PRO-ENDO K-FILE V200606025030 PRO-ENDO K-FILE V200606028006 PRO-ENDO K-FILE V200606028008 PRO-ENDO K-FILE V200606028010 PRO-ENDO K-FILE V200606028015 PRO-ENDO K-FILE V200606028020 PRO-ENDO K-FILE V200606028025 PRO-ENDO K-FILE V200606028030 PRO-ENDO K-FILE V200606031006 PRO-ENDO K-FILE V200606031008 PRO-ENDO K-FILE V200606031010 PRO-ENDO K-FILE V200606031015 PRO-ENDO K-FILE V200606031020 PRO-ENDO K-FILE V200606031025 PRO-ENDO K-FILE V200606031030	☐ 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 I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
++E22510047DN Device name and article number: GUTTAFUSION SIZE VERIFIER 20; 6 PCS V041508000020 GUTTAFUSION SIZE VERIFIER 25; 6 PCS V041508000025 GUTTAFUSION SIZE VERIFIER 30; 6 PCS V041508000030 GUTTAFUSION SIZE VERIFIER 35; 6 PCS V041508000035 GUTTAFUSION SIZE VERIFIER 40; 6 PCS V041508000040 GUTTAFUSION SIZE VERIFIER 45; 6 PCS V041508000045 GUTTAFUSION SIZE VERIFIER 50; 6 PCS V041508000050	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ 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 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
GUTTAFUSION SIZE VERIFIER 55; 6 PCS GUTTAFUSION SIZE VERIFIER ASSORTMENT	V041508000055 V041508000305	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/24	200130017391	Initial issue
2024/07/24	200130024598	Update due to change notification (++E22510021D4) Correction of classification (++E22510047DN, class IIa)
2025/01/09	200130046851	Update due to extended SKUs