

# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

### EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

## Directa AB

Finvids väg 8, SE- 194 27 Upplands Väsby, Sweden

Manufacturer SRN: SE-MF-000002500

### Scope:

Dental instruments

**Certificate Number:**

28620139228

**Initial Certification Date:**

9 January 2023

**Date of Certification Decision:**

9 January 2023

**Certificate Issue Date:**

9 January 2023

**Certificate Expiry Date:**

26 December 2027



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Brian Mather  
Certification Authority, MDR  
Intertek Medical Notified Body AB,  
Torshamnsgatan 43,  
Box 1103, SE-164 22 Kista, Sweden

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

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**PRODUCT LIST FOR CERTIFICATE**  
*See attached Product List*

**EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD00174-01 Directa AB Sendoline Big Apical Files BAF
Audit Report Reference	Stage 1 – DELTA audit ACTY-2022-524934
	Stage 2 – DELTA audit ACTY-2022-524936

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.




## PRODUCT LIST FOR CERTIFICATE

**Issued to:** Directa AB  
**Certificate number:** 28620139228  
**Certificate valid from:** 2023-01-09

**Product List Issue Date:**  
 27 December 2023

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
<b>Class I reusable surgical instruments</b>			
<i>Basic UDI-DI: 731023999528B8</i>			
DE3 TIN - Luxator Dual Edge Periotome Titanium	Class I(r) Q010399		2023-01-09
DE3 - Luxator Dual Edge Periotome	Class I(r) Q010399		2023-01-09
DE5 - Luxator Dual Edge Periotome	Class I(r) Q010399		2023-01-09
F25 - Luxator Forte Elevator	Class I(r) Q010399		2023-01-09
F32C - Luxator Forte Elevator	Class I(r) Q010399		2023-01-09
F32 - Luxator Forte Elevator	Class I(r) Q010399		2023-01-09
F40 - Luxator Forte Elevator	Class I(r) Q010399		2023-01-09
L1S - Luxator Periotome	Class I(r) Q010399		2023-01-09
L2S TIN - Luxator Periotome Titanium	Class I(r) Q010399		2023-01-09
L2S - Luxator Periotome	Class I(r) Q010399		2023-01-09
L3A TIN - Luxator Periotome Titanium	Class I(r) Q010399		2023-01-09
L3CA - Luxator Periotome	Class I(r) Q010399		2023-01-09
L3C - Luxator Periotome	Class I(r) Q010399		2023-01-09
L3IC - Luxator Periotome	Class I(r) Q010399		2023-01-09
L3S TIN - Luxator Periotome Titanium	Class I(r) Q010399		2023-01-09
L3S - Luxator Periotome	Class I(r) Q010399		2023-01-09
L5C - Luxator Periotome	Class I(r) Q010399		2023-01-09

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.



Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
L5S - Luxator Periotome	Class I(r) Q010399		2023-01-09
L-K VET - Luxator Periotome	Class I(r) Q010399		2023-01-09
L-K4 - Luxator Periotome	Class I(r) Q010399		2023-01-09
L-K7 - Luxator Periotome	Class I(r) Q010399		2023-01-09
P1 - Luxator P-series	Class I(r) Q010399		2023-01-09
P2 - Luxator P-series	Class I(r) Q010399		2023-01-09
P3 - Luxator P-series	Class I(r) Q010399		2023-01-09
P4 - Luxator P-series	Class I(r) Q010399		2023-01-09
P-kit - Luxator P-series	Class I(r) Q010399		2023-01-09
S2S - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
S3CA - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
S3C - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
S3S - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
S5S - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
SK4 - Luxator Short Periotome	Class I(r) Q010399		2023-01-09
<b>Dental instruments</b>			
<b>Basic UDI-DI: 731023999525B2</b>			
3521410BS - Sendoline K-Files STERILE 10 21 mm	Class IIa Q010507		2023-01-09
3521515BS - Sendoline K-Files STERILE 15 21 mm	Class IIa Q010507		2023-01-09
3525410BS - Sendoline K-Files STERILE 10 25 mm	Class IIa Q010507		2023-01-09
3525515BS - Sendoline K-Files STERILE 15 25 mm	Class IIa Q010507		2023-01-09
44230010BS - Sendoline S5 System STERILE Intro kit #1-5	Class IIa Q010507		2023-01-09
442320045BS - Sendoline S5 System STERILE #5 20/04 23 mm	Class IIa Q010507		2023-01-09

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product list issue date: 27 December 2023



Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
442325044BS - Sendoline S5 System STERILE #4 25/04 23 mm	Class IIa Q010507		2023-01-09
442330043BS - Sendoline S5 System STERILE #3 30/04 23 mm	Class IIa Q010507		2023-01-09
442330062BS - Sendoline S5 System STERILE #2 30/06 23 mm	Class IIa Q010507		2023-01-09
442330081BS - Sendoline S5 System STERILE #1 30/08 18 mm	Class IIa Q010507		2023-01-09
44234035BS - Sendoline Big Apical Files 35/04 23 mm	Class IIa Q010507		2023-01-09
44234040BS - Sendoline Big Apical Files 40/04 23 mm	Class IIa Q010507		2023-01-09
44234045BS - Sendoline Big Apical Files 45/04 23 mm	Class IIa Q010507		2023-01-09
44234050BS - Sendoline Big Apical Files 50/04 23 mm	Class IIa Q010507		2023-01-09
44280010BS - Sendoline S5 System STERILE Intro kit #1-5	Class IIa Q010507		2023-01-09
442820045BS - Sendoline S5 System STERILE #5 20/04 28 mm	Class IIa Q010507		2023-01-09
442825044BS - Sendoline S5 System STERILE #4 25/04 28 mm	Class IIa Q010507		2023-01-09
442830043BS - Sendoline S5 System STERILE #3 30/04 28 mm	Class IIa Q010507		2023-01-09
442830062BS - Sendoline S5 System STERILE #2 30/06 28 mm	Class IIa Q010507		2023-01-09
44284035BS - Sendoline Big Apical Files 35/04 28 mm	Class IIa Q010507		2023-01-09
44284040BS - Sendoline Big Apical Files 40/04 28 mm	Class IIa Q010507		2023-01-09
44284045BS - Sendoline Big Apical Files 45/04 28 mm	Class IIa Q010507		2023-01-09

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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44284050BS - Sendoline Big Apical Files 50/04 28 mm	Class IIa Q010507		2023-01-09
S1P01BS - Sendoline S1 Plus System Treatment Pack	Class IIa Q010507		2023-01-09
S1P251506BS - Sendoline S1 Plus System Small 15/06 25 mm	Class IIa Q010507		2023-01-09
S1P252506BS - Sendoline S1 Plus System Standard 25/06 25 mm	Class IIa Q010507		2023-01-09
S1P254004BS - Sendoline S1 Plus System Large 40/04 25 mm	Class IIa Q010507		2023-01-09
S1P311506BS - Sendoline S1 Plus System Small 15/06 31 mm	Class IIa Q010507		2023-01-09
S1P312506BS - Sendoline S1 Plus System Standard 25/06 31 mm	Class IIa Q010507		2023-01-09
S1P314004BS - Sendoline S1 Plus System Large 40/04 31 mm	Class IIa Q010507		2023-01-09
S301BS - Sendoline S3 System Assortment	Class IIa Q010507		2023-01-09
S3193008BS - Sendoline S3 System #1 30/08 19 mm	Class IIa Q010507		2023-01-09
S3252004BS - Sendoline S3 System Glidepath 20/04 25 mm	Class IIa Q010507		2023-01-09
S3253004BS - Sendoline S3 System #3 30/04 25 mm	Class IIa Q010507		2023-01-09
S3253006BS - Sendoline S3 System #2 30/06 25 mm	Class IIa Q010507		2023-01-09
S3312004BS - Sendoline S3 System Glidepath 20/04 31 mm	Class IIa Q010507		2023-01-09
S3313004BS - Sendoline S3 System #3 30/04 31 mm	Class IIa Q010507		2023-01-09
S3313006BS - Sendoline S3 System #2 30/06 31 mm	Class IIa Q010507		2023-01-09
<b>Basic UDI-DI: 731023999532AX</b>			
00047765 - H-File G line Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
00047771 - H-File G line 08 21 mm	Class IIa Q010507		2023-12-27
00047772 - H-File G line 10 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
00047774 - H-File G line 08 25 mm	Class IIa Q010507		2023-12-27
00047775 - H-File G line 10 25 mm	Class IIa Q010507		2023-12-27
00047777 - H-File G line 08 28 mm	Class IIa Q010507		2023-12-27
00047778 - H-File G line 10 28 mm	Class IIa Q010507		2023-12-27
00047779 - H-File G line 15 21 mm	Class IIa Q010507		2023-12-27
00047780 - H-File G line 20 21 mm	Class IIa Q010507		2023-12-27
00047781 - H-File G line 25 21 mm	Class IIa Q010507		2023-12-27
00047782 - H-File G line 30 21 mm	Class IIa Q010507		2023-12-27
00047783 - H-File G line 35 21 mm	Class IIa Q010507		2023-12-27
00047784 - H-File G line 40 21 mm	Class IIa Q010507		2023-12-27
00047792 - H-File G line 15 25 mm	Class IIa Q010507		2023-12-27
00047793 - H-File G line 20 25 mm	Class IIa Q010507		2023-12-27
00047794 - H-File G line 25 25 mm	Class IIa Q010507		2023-12-27
00047795 - H-File G line 30 25 mm	Class IIa Q010507		2023-12-27
00047796 - H-File G line 35 25 mm	Class IIa Q010507		2023-12-27
00047797 - H-File G line 40 25 mm	Class IIa Q010507		2023-12-27
00047798 - H-File G line 45 25 mm	Class IIa Q010507		2023-12-27
00047799 - H-File G line 50 25 mm	Class IIa Q010507		2023-12-27
00047800 - H-File G line 55 25 mm	Class IIa Q010507		2023-12-27
00047801 - H-File G line 60 25 mm	Class IIa Q010507		2023-12-27
00047804 - H-File G line 15 28 mm	Class IIa Q010507		2023-12-27
00047805 - H-File G line 20 28 mm	Class IIa Q010507		2023-12-27
00047806 - H-File G line 25 28 mm	Class IIa Q010507		2023-12-27
00047807 - H-File G line 30 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
00047808 - H-File G line 35 28 mm	Class IIa Q010507		2023-12-27
00047809 - H-File G line 40 28 mm	Class IIa Q010507		2023-12-27
00047813 - K-File G line Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
00047816 - K-File G line Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
00047818 - K-File G line 06 21 mm	Class IIa Q010507		2023-12-27
00047819 - K-File G line 08 21 mm	Class IIa Q010507		2023-12-27
00047820 - K-File G line 10 21 mm	Class IIa Q010507		2023-12-27
00047821 - K-File G line 06 25 mm	Class IIa Q010507		2023-12-27
00047822 - K-File G line 08 25 mm	Class IIa Q010507		2023-12-27
00047823 - K-File G line 10 25 mm	Class IIa Q010507		2023-12-27
00047824 - K-File G line 06 28 mm	Class IIa Q010507		2023-12-27
00047825 - K-File G line 08 28 mm	Class IIa Q010507		2023-12-27
00047826 - K-File G line 10 28 mm	Class IIa Q010507		2023-12-27
00047827 - K-File G line 15 21 mm	Class IIa Q010507		2023-12-27
00047828 - K-File G line 20 21 mm	Class IIa Q010507		2023-12-27
00047829 - K-File G line 25 21 mm	Class IIa Q010507		2023-12-27
00047830 - K-File G line 30 21 mm	Class IIa Q010507		2023-12-27
00047831 - K-File G line 35 21 mm	Class IIa Q010507		2023-12-27
00047832 - K-File G line 40 21 mm	Class IIa Q010507		2023-12-27
00047835 - K-File G line 15 25 mm	Class IIa Q010507		2023-12-27
00047836 - K-File G line 20 25 mm	Class IIa Q010507		2023-12-27
00047837 - K-File G line 25 25 mm	Class IIa Q010507		2023-12-27
00047838 - K-File G line 30 25 mm	Class IIa Q010507		2023-12-27
00047839 - K-File G line 35 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
00047840 - K-File G line 40 25 mm	Class IIa Q010507		2023-12-27
00047841 - K-File G line 45 25 mm	Class IIa Q010507		2023-12-27
00047842 - K-File G line 50 25 mm	Class IIa Q010507		2023-12-27
00047843 - K-File G line 55 25 mm	Class IIa Q010507		2023-12-27
00047844 - K-File G line 60 25 mm	Class IIa Q010507		2023-12-27
00047847 - K-File G line 15 28 mm	Class IIa Q010507		2023-12-27
00047848 - K-File G line 20 28 mm	Class IIa Q010507		2023-12-27
00047849 - K-File G line 25 28 mm	Class IIa Q010507		2023-12-27
00047850 - K-File G line 30 28 mm	Class IIa Q010507		2023-12-27
00047851 - K-File G line 35 28 mm	Class IIa Q010507		2023-12-27
00047852 - K-File G line 40 28 mm	Class IIa Q010507		2023-12-27
00047856 - K-Reamer G line Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
00047861 - K-Reamer G line 06 21 mm	Class IIa Q010507		2023-12-27
00047862 - K-Reamer G line 08 21 mm	Class IIa Q010507		2023-12-27
00047863 - K-Reamer G line 10 21 mm	Class IIa Q010507		2023-12-27
00047864 - K-Reamer G line 06 25 mm	Class IIa Q010507		2023-12-27
00047865 - K-Reamer G line 08 25 mm	Class IIa Q010507		2023-12-27
00047866 - K-Reamer G line 10 25 mm	Class IIa Q010507		2023-12-27
00047867 - K-Reamer G line 06 28 mm	Class IIa Q010507		2023-12-27
00047868 - K-Reamer G line 08 28 mm	Class IIa Q010507		2023-12-27
00047869 - K-Reamer G line 10 28 mm	Class IIa Q010507		2023-12-27
00047870 - K-Reamer G line 15 21 mm	Class IIa Q010507		2023-12-27
00047871 - K-Reamer G line 20 21 mm	Class IIa Q010507		2023-12-27
00047872 - K-Reamer G line 25 21 mm	Class IIa Q010507		2023-12-27

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00047873 - K-Reamer G line 30 21 mm	Class IIa Q010507		2023-12-27
00047874 - K-Reamer G line 35 21 mm	Class IIa Q010507		2023-12-27
00047875 - K-Reamer G line 40 21 mm	Class IIa Q010507		2023-12-27
00047878 - K-Reamer G line 15 25 mm	Class IIa Q010507		2023-12-27
00047879 - K-Reamer G line 20 25 mm	Class IIa Q010507		2023-12-27
00047880 - K-Reamer G line 25 25 mm	Class IIa Q010507		2023-12-27
00047881 - K-Reamer G line 30 25 mm	Class IIa Q010507		2023-12-27
00047882 - K-Reamer G line 35 25 mm	Class IIa Q010507		2023-12-27
00047883 - K-Reamer G line 40 25 mm	Class IIa Q010507		2023-12-27
00047884 - K-Reamer G line 45 25 mm	Class IIa Q010507		2023-12-27
00047885 - K-Reamer G line 50 25 mm	Class IIa Q010507		2023-12-27
00047887 - K-Reamer G line 60 25 mm	Class IIa Q010507		2023-12-27
00047888 - K-Reamer G line 70 25 mm	Class IIa Q010507		2023-12-27
00047889 - K-Reamer G line 80 25 mm	Class IIa Q010507		2023-12-27
00047890 - K-Reamer G line 15 28 mm	Class IIa Q010507		2023-12-27
00047891 - K-Reamer G line 20 28 mm	Class IIa Q010507		2023-12-27
00047892 - K-Reamer G line 25 28 mm	Class IIa Q010507		2023-12-27
00047893 - K-Reamer G line 30 28 mm	Class IIa Q010507		2023-12-27
00047894 - K-Reamer G line 35 28 mm	Class IIa Q010507		2023-12-27
00047895 - K-Reamer G line 40 28 mm	Class IIa Q010507		2023-12-27
00082808 - K-Reamer G line 06 31 mm	Class IIa Q010507		2023-12-27
00082809 - K-Reamer G line 08 31 mm	Class IIa Q010507		2023-12-27
00082810 - K-Reamer G line 10 31 mm	Class IIa Q010507		2023-12-27
00082811 - K-Reamer G line 15 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
00082812 - K-Reamer G line 20 31 mm	Class IIa Q010507		2023-12-27
00082813 - K-Reamer G line 25 31 mm	Class IIa Q010507		2023-12-27
00082814 - K-Reamer G line 30 31 mm	Class IIa Q010507		2023-12-27
00082815 - K-Reamer G line 35 31 mm	Class IIa Q010507		2023-12-27
00082816 - K-Reamer G line 40 31 mm	Class IIa Q010507		2023-12-27
00082818 - K-File G line 06 31 mm	Class IIa Q010507		2023-12-27
00082819 - K-File G line 08 31 mm	Class IIa Q010507		2023-12-27
00082820 - K-File G line 10 31 mm	Class IIa Q010507		2023-12-27
00082821 - K-File G line 15 31 mm	Class IIa Q010507		2023-12-27
00082822 - K-File G line 20 31 mm	Class IIa Q010507		2023-12-27
00082823 - K-File G line 25 31 mm	Class IIa Q010507		2023-12-27
00082824 - K-File G line 30 31 mm	Class IIa Q010507		2023-12-27
00082825 - K-File G line 35 31 mm	Class IIa Q010507		2023-12-27
00082826 - K-File G line 40 31 mm	Class IIa Q010507		2023-12-27
00082827 - K-File G line 45 31 mm	Class IIa Q010507		2023-12-27
00082828 - K-File G line 50 31 mm	Class IIa Q010507		2023-12-27
00082829 - H-File G line 08 31 mm	Class IIa Q010507		2023-12-27
00082830 - H-File G line 10 31 mm	Class IIa Q010507		2023-12-27
00082831 - H-File G line 15 31 mm	Class IIa Q010507		2023-12-27
00082832 - H-File G line 20 31 mm	Class IIa Q010507		2023-12-27
00082833 - H-File G line 25 31 mm	Class IIa Q010507		2023-12-27
00082834 - H-File G line 30 31 mm	Class IIa Q010507		2023-12-27
00082835 - H-File G line 35 31 mm	Class IIa Q010507		2023-12-27
00082836 - H-File G line 40 31 mm	Class IIa Q010507		2023-12-27

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00082837 - H-File G line 45 31 mm	Class IIa Q010507		2023-12-27
00082838 - H-File G line 50 31 mm	Class IIa Q010507		2023-12-27
00105874 - K-File G line 60 21 mm	Class IIa Q010507		2023-12-27
124153 - Smart Hedströmfeile 08 21 mm	Class IIa Q010507		2023-12-27
124154 - Smart Hedströmfeile 08 25 mm	Class IIa Q010507		2023-12-27
124155 - Smart Hedströmfeile 08 31 mm	Class IIa Q010507		2023-12-27
124156 - Smart Hedströmfeile 10 21 mm	Class IIa Q010507		2023-12-27
124157 - Smart Hedströmfeile 10 25 mm	Class IIa Q010507		2023-12-27
124158 - Smart Hedströmfeile 10 31 mm	Class IIa Q010507		2023-12-27
124159 - Smart Hedströmfeile 15 21 mm	Class IIa Q010507		2023-12-27
124160 - Smart Hedströmfeile 15 25 mm	Class IIa Q010507		2023-12-27
124161 - Smart Hedströmfeile 15 31 mm	Class IIa Q010507		2023-12-27
124162 - Smart Hedströmfeile 20 21 mm	Class IIa Q010507		2023-12-27
124163 - Smart Hedströmfeile 20 25 mm	Class IIa Q010507		2023-12-27
124164 - Smart Hedströmfeile 20 31 mm	Class IIa Q010507		2023-12-27
124165 - Smart Hedströmfeile 25 21 mm	Class IIa Q010507		2023-12-27
124166 - Smart Hedströmfeile 25 25 mm	Class IIa Q010507		2023-12-27
124167 - Smart Hedströmfeile 25 31 mm	Class IIa Q010507		2023-12-27
124168 - Smart Hedströmfeile 30 21 mm	Class IIa Q010507		2023-12-27
124169 - Smart Hedströmfeile 30 25 mm	Class IIa Q010507		2023-12-27
124505 - Smart Hedströmfeile 30 31 mm	Class IIa Q010507		2023-12-27
124551 - Smart Hedströmfeile 35 21 mm	Class IIa Q010507		2023-12-27
124552 - Smart Hedströmfeile 35 25 mm	Class IIa Q010507		2023-12-27
124553 - Smart Hedströmfeile 35 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
124554 - Smart Hedströmfeile 40 21 mm	Class IIa Q010507		2023-12-27
124555 - Smart Hedströmfeile 40 25 mm	Class IIa Q010507		2023-12-27
124556 - Smart Hedströmfeile 40 31 mm	Class IIa Q010507		2023-12-27
124557 - Smart Hedströmfeile 45 21 mm	Class IIa Q010507		2023-12-27
124558 - Smart Hedströmfeile 45 25 mm	Class IIa Q010507		2023-12-27
124559 - Smart Hedströmfeile 45 31 mm	Class IIa Q010507		2023-12-27
124566 - Smart Hedströmfeile 50 31 mm	Class IIa Q010507		2023-12-27
124786 - Smart Hedströmfeile 50 21 mm	Class IIa Q010507		2023-12-27
124787 - Smart Hedströmfeile 50 25 mm	Class IIa Q010507		2023-12-27
124788 - Smart Hedströmfeile Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
124789 - Smart Hedströmfeile Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
124790 - Smart Hedströmfeile Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
124791 - Smart Hedströmfeile Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
124792 - Smart Hedströmfeile Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
124793 - Smart Hedströmfeile Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
124794 - Smart K-Bohrer 10 21 mm	Class IIa Q010507		2023-12-27
124795 - Smart K-Bohrer 10 25 mm	Class IIa Q010507		2023-12-27
124796 - Smart K-Bohrer 10 31 mm	Class IIa Q010507		2023-12-27
124797 - Smart K-Bohrer 15 21 mm	Class IIa Q010507		2023-12-27
124798 - Smart K-Bohrer 15 25 mm	Class IIa Q010507		2023-12-27
124799 - Smart K-Bohrer 15 31 mm	Class IIa Q010507		2023-12-27
124800 - Smart K-Bohrer 20 21 mm	Class IIa Q010507		2023-12-27
124801 - Smart K-Bohrer 20 25 mm	Class IIa Q010507		2023-12-27
124802 - Smart K-Bohrer 20 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
124803 - Smart K-Bohrer 25 21 mm	Class IIa Q010507		2023-12-27
124804 - Smart K-Bohrer 25 25 mm	Class IIa Q010507		2023-12-27
124805 - Smart K-Bohrer 25 31 mm	Class IIa Q010507		2023-12-27
124806 - Smart K-Bohrer 30 21 mm	Class IIa Q010507		2023-12-27
124807 - Smart K-Bohrer 30 25 mm	Class IIa Q010507		2023-12-27
124808 - Smart K-Bohrer 30 31 mm	Class IIa Q010507		2023-12-27
124809 - Smart K-Bohrer 35 21 mm	Class IIa Q010507		2023-12-27
124810 - Smart K-Bohrer 35 25 mm	Class IIa Q010507		2023-12-27
124811 - Smart K-Bohrer 35 31 mm	Class IIa Q010507		2023-12-27
124812 - Smart K-Bohrer 40 21 mm	Class IIa Q010507		2023-12-27
124813 - Smart K-Bohrer 40 25 mm	Class IIa Q010507		2023-12-27
124814 - Smart K-Bohrer 40 31 mm	Class IIa Q010507		2023-12-27
124815 - Smart K-Bohrer 45 21 mm	Class IIa Q010507		2023-12-27
124816 - Smart K-Bohrer 45 25 mm	Class IIa Q010507		2023-12-27
124817 - Smart K-Bohrer 45 31 mm	Class IIa Q010507		2023-12-27
124818 - Smart K-Bohrer 50 21 mm	Class IIa Q010507		2023-12-27
124819 - Smart K-Bohrer 50 25 mm	Class IIa Q010507		2023-12-27
124820 - Smart K-Bohrer 50 31 mm	Class IIa Q010507		2023-12-27
124821 - Smart K-Bohrer 06 21 mm	Class IIa Q010507		2023-12-27
124822 - Smart K-Bohrer 06 25 mm	Class IIa Q010507		2023-12-27
124823 - Smart K-Bohrer 06 31 mm	Class IIa Q010507		2023-12-27
124824 - Smart K-Bohrer 08 21 mm	Class IIa Q010507		2023-12-27
124825 - Smart K-Bohrer 08 25 mm	Class IIa Q010507		2023-12-27
124826 - Smart K-Bohrer 08 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
124827 - Smart K-Bohrer Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
124828 - Smart K-Bohrer Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
124829 - Smart K-Bohrer Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
124830 - Smart K-Bohrer Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
124831 - Smart K-Bohrer Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
124832 - Smart K-Bohrer Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
124833 - Smart K-Feile 10 21 mm	Class IIa Q010507		2023-12-27
124834 - Smart K-Feile 10 25 mm	Class IIa Q010507		2023-12-27
124835 - Smart K-Feile 06 31 mm	Class IIa Q010507		2023-12-27
124836 - Smart K-Feile 15 21 mm	Class IIa Q010507		2023-12-27
124837 - Smart K-Feile 15 25 mm	Class IIa Q010507		2023-12-27
124838 - Smart K-Feile 08 31 mm	Class IIa Q010507		2023-12-27
124839 - Smart K-Feile 20 21 mm	Class IIa Q010507		2023-12-27
124840 - Smart K-Feile 20 25 mm	Class IIa Q010507		2023-12-27
124841 - Smart K-Feile 10 31 mm	Class IIa Q010507		2023-12-27
124842 - Smart K-Feile 25 21 mm	Class IIa Q010507		2023-12-27
124843 - Smart K-Feile 25 25 mm	Class IIa Q010507		2023-12-27
124844 - Smart K-Feile 15 31 mm	Class IIa Q010507		2023-12-27
124845 - Smart K-Feile 30 21 mm	Class IIa Q010507		2023-12-27
124846 - Smart K-Feile 30 25 mm	Class IIa Q010507		2023-12-27
124847 - Smart K-Feile 20 31 mm	Class IIa Q010507		2023-12-27
124848 - Smart K-Feile 35 21 mm	Class IIa Q010507		2023-12-27
124849 - Smart K-Feile 35 25 mm	Class IIa Q010507		2023-12-27
124850 - Smart K-Feile 25 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
124851 - Smart K-Feile 40 21 mm	Class IIa Q010507		2023-12-27
124852 - Smart K-Feile 40 25 mm	Class IIa Q010507		2023-12-27
124853 - Smart K-Feile 30 31 mm	Class IIa Q010507		2023-12-27
124854 - Smart K-Feile 45 21 mm	Class IIa Q010507		2023-12-27
124855 - Smart K-Feile 45 25 mm	Class IIa Q010507		2023-12-27
124856 - Smart K-Feile 35 31 mm	Class IIa Q010507		2023-12-27
124857 - Smart K-Feile 50 21 mm	Class IIa Q010507		2023-12-27
124858 - Smart K-Feile 50 25 mm	Class IIa Q010507		2023-12-27
124859 - Smart K-Feile 40 31 mm	Class IIa Q010507		2023-12-27
124860 - Smart K-Feile 06 21 mm	Class IIa Q010507		2023-12-27
124861 - Smart K-Feile 06 25 mm	Class IIa Q010507		2023-12-27
124862 - Smart K-Feile 45 31 mm	Class IIa Q010507		2023-12-27
124863 - Smart K-Feile 08 21 mm	Class IIa Q010507		2023-12-27
124864 - Smart K-Feile 08 25 mm	Class IIa Q010507		2023-12-27
124865 - Smart K-Feile 50 31 mm	Class IIa Q010507		2023-12-27
124866 - Smart K-Feile Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
124867 - Smart K-Feile Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
124868 - Smart K-Feile Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
124869 - Smart K-Feile Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
124870 - Smart K-Feile Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
124871 - Smart K-Feile Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
243760 - Pluline Hedströmfeile 08 21 mm	Class IIa Q010507		2023-12-27
243761 - Pluline Hedströmfeile 10 21 mm	Class IIa Q010507		2023-12-27
243762 - Pluline Hedströmfeile 15 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
243763 - Pluline Hedströmfeile 20 21 mm	Class IIa Q010507		2023-12-27
243764 - Pluline Hedströmfeile 25 21 mm	Class IIa Q010507		2023-12-27
243765 - Pluline Hedströmfeile 30 21 mm	Class IIa Q010507		2023-12-27
243766 - Pluline Hedströmfeile 35 21 mm	Class IIa Q010507		2023-12-27
243767 - Pluline Hedströmfeile 40 21 mm	Class IIa Q010507		2023-12-27
243768 - Pluline Hedströmfeile Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
243769 - Pluline Hedströmfeile 45 21 mm	Class IIa Q010507		2023-12-27
243770 - Pluline Hedströmfeile 50 21 mm	Class IIa Q010507		2023-12-27
243771 - Pluline Hedströmfeile Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
243772 - Pluline Hedströmfeile 08 25 mm	Class IIa Q010507		2023-12-27
243773 - Pluline Hedströmfeile 10 25 mm	Class IIa Q010507		2023-12-27
243774 - Pluline Hedströmfeile 15 25 mm	Class IIa Q010507		2023-12-27
243775 - Pluline Hedströmfeile 20 25 mm	Class IIa Q010507		2023-12-27
243776 - Pluline Hedströmfeile 25 25 mm	Class IIa Q010507		2023-12-27
243777 - Pluline Hedströmfeile 30 25 mm	Class IIa Q010507		2023-12-27
243778 - Pluline Hedströmfeile 35 25 mm	Class IIa Q010507		2023-12-27
243779 - Pluline Hedströmfeile 40 25 mm	Class IIa Q010507		2023-12-27
243780 - Pluline Hedströmfeile Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
243781 - Pluline Hedströmfeile 45 25 mm	Class IIa Q010507		2023-12-27
243782 - Pluline Hedströmfeile 50 25 mm	Class IIa Q010507		2023-12-27
243783 - Pluline Hedströmfeile Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
243784 - Pluline Hedströmfeile 08 31 mm	Class IIa Q010507		2023-12-27
243785 - Pluline Hedströmfeile 10 31 mm	Class IIa Q010507		2023-12-27
243786 - Pluline Hedströmfeile 15 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
243787 - Pluline Hedströmfeile 20 31 mm	Class IIa Q010507		2023-12-27
243788 - Pluline Hedströmfeile 25 31 mm	Class IIa Q010507		2023-12-27
243789 - Pluline Hedströmfeile 30 31 mm	Class IIa Q010507		2023-12-27
243790 - Pluline Hedströmfeile 35 31 mm	Class IIa Q010507		2023-12-27
243791 - Pluline Hedströmfeile 40 31 mm	Class IIa Q010507		2023-12-27
243792 - Pluline Hedströmfeile Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
243793 - Pluline Hedströmfeile 45 31 mm	Class IIa Q010507		2023-12-27
243794 - Pluline Hedströmfeile 50 31 mm	Class IIa Q010507		2023-12-27
243795 - Pluline Hedströmfeile Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
243796 - Pluline K-Feile 06 21 mm	Class IIa Q010507		2023-12-27
243797 - Pluline K-Feile 08 21 mm	Class IIa Q010507		2023-12-27
243798 - Pluline K-Feile 10 21 mm	Class IIa Q010507		2023-12-27
243799 - Pluline K-Feile 15 21 mm	Class IIa Q010507		2023-12-27
243800 - Pluline K-Feile 20 21 mm	Class IIa Q010507		2023-12-27
243801 - Pluline K-Feile 25 21 mm	Class IIa Q010507		2023-12-27
243802 - Pluline K-Feile 30 21 mm	Class IIa Q010507		2023-12-27
243803 - Pluline K-Feile 35 21 mm	Class IIa Q010507		2023-12-27
243804 - Pluline K-Feile 40 21 mm	Class IIa Q010507		2023-12-27
243805 - Pluline K-Feile Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
243806 - Pluline K-Feile 45 21 mm	Class IIa Q010507		2023-12-27
243807 - Pluline K-Feile 50 21 mm	Class IIa Q010507		2023-12-27
243808 - Pluline K-Feile Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
243809 - Pluline K-Feile 06 25 mm	Class IIa Q010507		2023-12-27
243810 - Pluline K-Feile 08 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
243811 - Pluline K-Feile 10 25 mm	Class IIa Q010507		2023-12-27
243812 - Pluline K-Feile 15 25 mm	Class IIa Q010507		2023-12-27
243813 - Pluline K-Feile 20 25 mm	Class IIa Q010507		2023-12-27
243814 - Pluline K-Feile 25 25 mm	Class IIa Q010507		2023-12-27
243815 - Pluline K-Feile 30 25 mm	Class IIa Q010507		2023-12-27
243816 - Pluline K-Feile 35 25 mm	Class IIa Q010507		2023-12-27
243817 - Pluline K-Feile 40 25 mm	Class IIa Q010507		2023-12-27
243818 - Pluline K-Feile Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
243819 - Pluline K-Feile 45 25 mm	Class IIa Q010507		2023-12-27
243820 - Pluline K-Feile 50 25 mm	Class IIa Q010507		2023-12-27
243821 - Pluline K-Feile Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
243822 - Pluline K-Feile 06 31 mm	Class IIa Q010507		2023-12-27
243823 - Pluline K-Feile 08 31 mm	Class IIa Q010507		2023-12-27
243824 - Pluline K-Feile 10 31 mm	Class IIa Q010507		2023-12-27
243825 - Pluline K-Feile 15 31 mm	Class IIa Q010507		2023-12-27
243826 - Pluline K-Feile 20 31 mm	Class IIa Q010507		2023-12-27
243827 - Pluline K-Feile 25 31 mm	Class IIa Q010507		2023-12-27
243828 - Pluline K-Feile 30 31 mm	Class IIa Q010507		2023-12-27
243829 - Pluline K-Feile 35 31 mm	Class IIa Q010507		2023-12-27
243830 - Pluline K-Feile 40 31 mm	Class IIa Q010507		2023-12-27
243831 - Pluline K-Feile Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
243832 - Pluline K-Feile 45 31 mm	Class IIa Q010507		2023-12-27
243833 - Pluline K-Feile 50 31 mm	Class IIa Q010507		2023-12-27
243834 - Pluline K-Feile Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
243835 - Pluline K-Bohrer 06 21 mm	Class IIa Q010507		2023-12-27
243836 - Pluline K-Bohrer 08 21 mm	Class IIa Q010507		2023-12-27
243837 - Pluline K-Bohrer 10 21 mm	Class IIa Q010507		2023-12-27
243838 - Pluline K-Bohrer 15 21 mm	Class IIa Q010507		2023-12-27
243839 - Pluline K-Bohrer 20 21 mm	Class IIa Q010507		2023-12-27
243840 - Pluline K-Bohrer 25 21 mm	Class IIa Q010507		2023-12-27
243841 - Pluline K-Bohrer 30 21 mm	Class IIa Q010507		2023-12-27
243842 - Pluline K-Bohrer 35 21 mm	Class IIa Q010507		2023-12-27
243843 - Pluline K-Bohrer 40 21 mm	Class IIa Q010507		2023-12-27
243844 - Pluline K-Bohrer Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
243845 - Pluline K-Bohrer 45 21 mm	Class IIa Q010507		2023-12-27
243846 - Pluline K-Bohrer 50 21 mm	Class IIa Q010507		2023-12-27
243847 - Pluline K-Bohrer Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
243848 - Pluline K-Bohrer 06 25 mm	Class IIa Q010507		2023-12-27
243849 - Pluline K-Bohrer 08 25 mm	Class IIa Q010507		2023-12-27
243850 - Pluline K-Bohrer 10 25 mm	Class IIa Q010507		2023-12-27
243851 - Pluline K-Bohrer 15 25 mm	Class IIa Q010507		2023-12-27
243852 - Pluline K-Bohrer 20 25 mm	Class IIa Q010507		2023-12-27
243853 - Pluline K-Bohrer 25 25 mm	Class IIa Q010507		2023-12-27
243854 - Pluline K-Bohrer 30 25 mm	Class IIa Q010507		2023-12-27
243855 - Pluline K-Bohrer 35 25 mm	Class IIa Q010507		2023-12-27
243856 - Pluline K-Bohrer 40 25 mm	Class IIa Q010507		2023-12-27
243857 - Pluline K-Bohrer Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
243858 - Pluline K-Bohrer 45 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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243859 - Pluline K-Bohrer 50 25 mm	Class IIa Q010507		2023-12-27
243860 - Pluline K-Bohrer Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
243861 - Pluline K-Bohrer 06 31 mm	Class IIa Q010507		2023-12-27
243862 - Pluline K-Bohrer 08 31 mm	Class IIa Q010507		2023-12-27
243863 - Pluline K-Bohrer 10 31 mm	Class IIa Q010507		2023-12-27
243864 - Pluline K-Bohrer 15 31 mm	Class IIa Q010507		2023-12-27
243865 - Pluline K-Bohrer 20 31 mm	Class IIa Q010507		2023-12-27
243866 - Pluline K-Bohrer 25 31 mm	Class IIa Q010507		2023-12-27
243867 - Pluline K-Bohrer 30 31 mm	Class IIa Q010507		2023-12-27
243868 - Pluline K-Bohrer 35 31 mm	Class IIa Q010507		2023-12-27
243869 - Pluline K-Bohrer 40 31 mm	Class IIa Q010507		2023-12-27
243870 - Pluline K-Bohrer Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
243871 - Pluline K-Bohrer 45 31 mm	Class IIa Q010507		2023-12-27
243872 - Pluline K-Bohrer 50 31 mm	Class IIa Q010507		2023-12-27
243873 - Pluline K-Bohrer Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
3221000B - Sendoline H-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
3221001B - Sendoline H-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
3221002B - Sendoline H-File Assorted 90-140 21 mm	Class IIa Q010507		2023-12-27
3221006B - Sendoline H-File 06 21 mm	Class IIa Q010507		2023-12-27
3221008B - Sendoline H-File 08 21 mm	Class IIa Q010507		2023-12-27
3221010B - Sendoline H-File 10 21 mm	Class IIa Q010507		2023-12-27
3221015B - Sendoline H-File 15 21 mm	Class IIa Q010507		2023-12-27
3221020B - Sendoline H-File 20 21 mm	Class IIa Q010507		2023-12-27
3221025B - Sendoline H-File 25 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3221030B - Sendoline H-File 30 21 mm	Class IIa Q010507		2023-12-27
3221035B - Sendoline H-File 35 21 mm	Class IIa Q010507		2023-12-27
3221040B - Sendoline H-File 40 21 mm	Class IIa Q010507		2023-12-27
3221045B - Sendoline H-File 45 21 mm	Class IIa Q010507		2023-12-27
3221050B - Sendoline H-File 50 21 mm	Class IIa Q010507		2023-12-27
3221055B - Sendoline H-File 55 21 mm	Class IIa Q010507		2023-12-27
3221060B - Sendoline H-File 60 21 mm	Class IIa Q010507		2023-12-27
3221070B - Sendoline H-File 70 21 mm	Class IIa Q010507		2023-12-27
3221080B - Sendoline H-File 80 21 mm	Class IIa Q010507		2023-12-27
3221090B - Sendoline H-File 90 21 mm	Class IIa Q010507		2023-12-27
3221100B - Sendoline H-File 100 21 mm	Class IIa Q010507		2023-12-27
3221110B - Sendoline H-File 110 21 mm	Class IIa Q010507		2023-12-27
3221120B - Sendoline H-File 120 21 mm	Class IIa Q010507		2023-12-27
3221130B - Sendoline H-File 130 21 mm	Class IIa Q010507		2023-12-27
3221140B - Sendoline H-File 140 21 mm	Class IIa Q010507		2023-12-27
3225000B - Sendoline H-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3225001B - Sendoline H-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
3225002B - Sendoline H-File Assorted 90-140 25 mm	Class IIa Q010507		2023-12-27
3225006B - Sendoline H-File 06 25 mm	Class IIa Q010507		2023-12-27
3225008B - Sendoline H-File 08 25 mm	Class IIa Q010507		2023-12-27
3225010B - Sendoline H-File 10 25 mm	Class IIa Q010507		2023-12-27
3225015B - Sendoline H-File 15 25 mm	Class IIa Q010507		2023-12-27
3225020B - Sendoline H-File 20 25 mm	Class IIa Q010507		2023-12-27
3225025B - Sendoline H-File 25 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3225030B - Sendoline H-File 30 25 mm	Class IIa Q010507		2023-12-27
3225035B - Sendoline H-File 35 25 mm	Class IIa Q010507		2023-12-27
3225040B - Sendoline H-File 40 25 mm	Class IIa Q010507		2023-12-27
3225045B - Sendoline H-File 45 25 mm	Class IIa Q010507		2023-12-27
3225050B - Sendoline H-File 50 25 mm	Class IIa Q010507		2023-12-27
3225055B - Sendoline H-File 55 25 mm	Class IIa Q010507		2023-12-27
3225060B - Sendoline H-File 60 25 mm	Class IIa Q010507		2023-12-27
3225070B - Sendoline H-File 70 25 mm	Class IIa Q010507		2023-12-27
3225080B - Sendoline H-File 80 25 mm	Class IIa Q010507		2023-12-27
3225090B - Sendoline H-File 90 25 mm	Class IIa Q010507		2023-12-27
3225100B - Sendoline H-File 100 25 mm	Class IIa Q010507		2023-12-27
3225110B - Sendoline H-File 110 25 mm	Class IIa Q010507		2023-12-27
3225120B - Sendoline H-File 120 25 mm	Class IIa Q010507		2023-12-27
3225130B - Sendoline H-File 130 25 mm	Class IIa Q010507		2023-12-27
3225140B - Sendoline H-File 140 25 mm	Class IIa Q010507		2023-12-27
3228000B - Sendoline H-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
3228001B - Sendoline H-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
3228002B - Sendoline H-File Assorted 90-140 28 mm	Class IIa Q010507		2023-12-27
3228006B - Sendoline H-File 06 28 mm	Class IIa Q010507		2023-12-27
3228008B - Sendoline H-File 08 28 mm	Class IIa Q010507		2023-12-27
3228010B - Sendoline H-File 10 28 mm	Class IIa Q010507		2023-12-27
3228015B - Sendoline H-File 15 28 mm	Class IIa Q010507		2023-12-27
3228020B - Sendoline H-File 20 28 mm	Class IIa Q010507		2023-12-27
3228025B - Sendoline H-File 25 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3228030B - Sendoline H-File 30 28 mm	Class IIa Q010507		2023-12-27
3228035B - Sendoline H-File 35 28 mm	Class IIa Q010507		2023-12-27
3228040B - Sendoline H-File 40 28 mm	Class IIa Q010507		2023-12-27
3228045B - Sendoline H-File 45 28 mm	Class IIa Q010507		2023-12-27
3228050B - Sendoline H-File 50 28 mm	Class IIa Q010507		2023-12-27
3228055B - Sendoline H-File 55 28 mm	Class IIa Q010507		2023-12-27
3228060B - Sendoline H-File 60 28 mm	Class IIa Q010507		2023-12-27
3228070B - Sendoline H-File 70 28 mm	Class IIa Q010507		2023-12-27
3228080B - Sendoline H-File 80 28 mm	Class IIa Q010507		2023-12-27
3228090B - Sendoline H-File 90 28 mm	Class IIa Q010507		2023-12-27
3228100B - Sendoline H-File 100 28 mm	Class IIa Q010507		2023-12-27
3228110B - Sendoline H-File 110 28 mm	Class IIa Q010507		2023-12-27
3228120B - Sendoline H-File 120 28 mm	Class IIa Q010507		2023-12-27
3228130B - Sendoline H-File 130 28 mm	Class IIa Q010507		2023-12-27
3228140B - Sendoline H-File 140 28 mm	Class IIa Q010507		2023-12-27
3231000B - Sendoline H-File Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
3231001B - Sendoline H-File Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
3231002B - Sendoline H-File Assorted 90-140 31 mm	Class IIa Q010507		2023-12-27
3231006B - Sendoline H-File 06 31 mm	Class IIa Q010507		2023-12-27
3231008B - Sendoline H-File 08 31 mm	Class IIa Q010507		2023-12-27
3231010B - Sendoline H-File 10 31 mm	Class IIa Q010507		2023-12-27
3231015B - Sendoline H-File 15 31 mm	Class IIa Q010507		2023-12-27
3231020B - Sendoline H-File 20 31 mm	Class IIa Q010507		2023-12-27
3231025B - Sendoline H-File 25 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3231030B - Sendoline H-File 30 31 mm	Class IIa Q010507		2023-12-27
3231035B - Sendoline H-File 35 31 mm	Class IIa Q010507		2023-12-27
3231040B - Sendoline H-File 40 31 mm	Class IIa Q010507		2023-12-27
3231045B - Sendoline H-File 45 31 mm	Class IIa Q010507		2023-12-27
3231050B - Sendoline H-File 50 31 mm	Class IIa Q010507		2023-12-27
3231055B - Sendoline H-File 55 31 mm	Class IIa Q010507		2023-12-27
3231060B - Sendoline H-File 60 31 mm	Class IIa Q010507		2023-12-27
3231070B - Sendoline H-File 70 31 mm	Class IIa Q010507		2023-12-27
3231080B - Sendoline H-File 80 31 mm	Class IIa Q010507		2023-12-27
3231090B - Sendoline H-File 90 31 mm	Class IIa Q010507		2023-12-27
3231100B - Sendoline H-File 100 31 mm	Class IIa Q010507		2023-12-27
3231110B - Sendoline H-File 110 31 mm	Class IIa Q010507		2023-12-27
3231120B - Sendoline H-File 120 31 mm	Class IIa Q010507		2023-12-27
3231130B - Sendoline H-File 130 31 mm	Class IIa Q010507		2023-12-27
3231140B - Sendoline H-File 140 31 mm	Class IIa Q010507		2023-12-27
3330000B - Sendoline Barbed Broaches Assorted #1-#6 25 mm	Class IIa Q010507		2023-12-27
3330100B - Sendoline Barbed Broaches #0 25 mm	Class IIa Q010507		2023-12-27
3330101B - Sendoline Barbed Broaches #1 25 mm	Class IIa Q010507		2023-12-27
3330102B - Sendoline Barbed Broaches #2 25 mm	Class IIa Q010507		2023-12-27
3330103B - Sendoline Barbed Broaches #3 25 mm	Class IIa Q010507		2023-12-27
3330104B - Sendoline Barbed Broaches #4 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3330105B - Sendoline Barbed Broaches #5 25 mm	Class IIa Q010507		2023-12-27
3330106B - Sendoline Barbed Broaches #6 25 mm	Class IIa Q010507		2023-12-27
3370020B - Sendoline NiTi Finger Plugger 20 25 mm	Class IIa Q010507		2023-12-27
3370030B - Sendoline NiTi Finger Plugger 30 25 mm	Class IIa Q010507		2023-12-27
3370040B - Sendoline NiTi Finger Plugger 40 25 mm	Class IIa Q010507		2023-12-27
3370050B - Sendoline NiTi Finger Plugger 50 25 mm	Class IIa Q010507		2023-12-27
3370060B - Sendoline NiTi Finger Plugger 60 25 mm	Class IIa Q010507		2023-12-27
3370070B - Sendoline NiTi Finger Plugger 70 25 mm	Class IIa Q010507		2023-12-27
3370080B - Sendoline NiTi Finger Plugger 80 25 mm	Class IIa Q010507		2023-12-27
3370100B - Sendoline NiTi Finger Plugger Assorted 20, 30, 40, 50, 60, 80 25 mm	Class IIa Q010507		2023-12-27
3380020B - Sendoline Finger Plugger 20 25 mm	Class IIa Q010507		2023-12-27
3380030B - Sendoline Finger Plugger 30 25 mm	Class IIa Q010507		2023-12-27
3380040B - Sendoline Finger Plugger 40 25 mm	Class IIa Q010507		2023-12-27
3380050B - Sendoline Finger Plugger 50 25 mm	Class IIa Q010507		2023-12-27
3380060B - Sendoline Finger Plugger 60 25 mm	Class IIa Q010507		2023-12-27
3380070B - Sendoline Finger Plugger 70 25 mm	Class IIa Q010507		2023-12-27
3380080B - Sendoline Finger Plugger 80 25 mm	Class IIa Q010507		2023-12-27
3380100B - Sendoline Finger Plugger Assorted 20, 30, 40, 50, 60, 80 25 mm	Class IIa Q010507		2023-12-27
3380105B - Sendoline Finger Plugger Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3385000B - Sendoline Finger Spreader Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3385015B - Sendoline Finger Spreader 15 25 mm	Class IIa Q010507		2023-12-27
3385020B - Sendoline Finger Spreader 20 25 mm	Class IIa Q010507		2023-12-27
3385025B - Sendoline Finger Spreader 25 25 mm	Class IIa Q010507		2023-12-27
3385030B - Sendoline Finger Spreader 30 25 mm	Class IIa Q010507		2023-12-27
3385035B - Sendoline Finger Spreader 35 25 mm	Class IIa Q010507		2023-12-27
3385040B - Sendoline Finger Spreader 40 25 mm	Class IIa Q010507		2023-12-27
3386000B - Sendoline NiTi Finger Spreader Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3386015B - Sendoline NiTi Finger Spreader 15 25 mm	Class IIa Q010507		2023-12-27
3386020B - Sendoline NiTi Finger Spreader 20 25 mm	Class IIa Q010507		2023-12-27
3386025B - Sendoline NiTi Finger Spreader 25 25 mm	Class IIa Q010507		2023-12-27
3386030B - Sendoline NiTi Finger Spreader 30 25 mm	Class IIa Q010507		2023-12-27
3386035B - Sendoline NiTi Finger Spreader 35 25 mm	Class IIa Q010507		2023-12-27
3386040B - Sendoline NiTi Finger Spreader 40 25 mm	Class IIa Q010507		2023-12-27
3418010B - Sendoline F-Finder 10 18 mm	Class IIa Q010507		2023-12-27
3421010B - Sendoline F-Finder 10 21 mm	Class IIa Q010507		2023-12-27
3521000B - Sendoline K-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
3521001B - Sendoline K-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
3521002B - Sendoline K-File Assorted 90-140 21 mm	Class IIa Q010507		2023-12-27
3521006B - Sendoline K-File 06 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3521008B - Sendoline K-File 08 21 mm	Class IIa Q010507		2023-12-27
3521010B - Sendoline K-File 10 21 mm	Class IIa Q010507		2023-12-27
3521015B - Sendoline K-File 15 21 mm	Class IIa Q010507		2023-12-27
3521020B - Sendoline K-File 20 21 mm	Class IIa Q010507		2023-12-27
3521025B - Sendoline K-File 25 21 mm	Class IIa Q010507		2023-12-27
3521030B - Sendoline K-File 30 21 mm	Class IIa Q010507		2023-12-27
3521035B - Sendoline K-File 35 21 mm	Class IIa Q010507		2023-12-27
3521040B - Sendoline K-File 40 21 mm	Class IIa Q010507		2023-12-27
3521045B - Sendoline K-File 45 21 mm	Class IIa Q010507		2023-12-27
3521050B - Sendoline K-File 50 21 mm	Class IIa Q010507		2023-12-27
3521055B - Sendoline K-File 55 21 mm	Class IIa Q010507		2023-12-27
3521060B - Sendoline K-File 60 21 mm	Class IIa Q010507		2023-12-27
3521070B - Sendoline K-File 70 21 mm	Class IIa Q010507		2023-12-27
3521080B - Sendoline K-File 80 21 mm	Class IIa Q010507		2023-12-27
3521090B - Sendoline K-File 90 21 mm	Class IIa Q010507		2023-12-27
3521100B - Sendoline K-File 100 21 mm	Class IIa Q010507		2023-12-27
3521110B - Sendoline K-File 110 21 mm	Class IIa Q010507		2023-12-27
3521120B - Sendoline K-File 120 21 mm	Class IIa Q010507		2023-12-27
3521130B - Sendoline K-File 130 21 mm	Class IIa Q010507		2023-12-27
3521140B - Sendoline K-File 140 21 mm	Class IIa Q010507		2023-12-27
3525000B - Sendoline K-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3525001B - Sendoline K-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
3525002B - Sendoline K-File Assorted 90-140 25 mm	Class IIa Q010507		2023-12-27
3525006B - Sendoline K-File 06 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3525008B - Sendoline K-File 08 25 mm	Class IIa Q010507		2023-12-27
3525010B - Sendoline K-File 10 25 mm	Class IIa Q010507		2023-12-27
3525015B - Sendoline K-File 15 25 mm	Class IIa Q010507		2023-12-27
3525020B - Sendoline K-File 20 25 mm	Class IIa Q010507		2023-12-27
3525025B - Sendoline K-File 25 25 mm	Class IIa Q010507		2023-12-27
3525030B - Sendoline K-File 30 25 mm	Class IIa Q010507		2023-12-27
3525035B - Sendoline K-File 35 25 mm	Class IIa Q010507		2023-12-27
3525040B - Sendoline K-File 40 25 mm	Class IIa Q010507		2023-12-27
3525045B - Sendoline K-File 45 25 mm	Class IIa Q010507		2023-12-27
3525050B - Sendoline K-File 50 25 mm	Class IIa Q010507		2023-12-27
3525055B - Sendoline K-File 55 25 mm	Class IIa Q010507		2023-12-27
3525060B - Sendoline K-File 60 25 mm	Class IIa Q010507		2023-12-27
3525070B - Sendoline K-File 70 25 mm	Class IIa Q010507		2023-12-27
3525080B - Sendoline K-File 80 25 mm	Class IIa Q010507		2023-12-27
3525090B - Sendoline K-File 90 25 mm	Class IIa Q010507		2023-12-27
3525100B - Sendoline K-File 100 25 mm	Class IIa Q010507		2023-12-27
3525110B - Sendoline K-File 110 25 mm	Class IIa Q010507		2023-12-27
3525120B - Sendoline K-File 120 25 mm	Class IIa Q010507		2023-12-27
3525130B - Sendoline K-File 130 25 mm	Class IIa Q010507		2023-12-27
3525140B - Sendoline K-File 140 25 mm	Class IIa Q010507		2023-12-27
3528000B - Sendoline K-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
3528001B - Sendoline K-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
3528002B - Sendoline K-File Assorted 90-140 28 mm	Class IIa Q010507		2023-12-27
3528006B - Sendoline K-File 06 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3528008B - Sendoline K-File 08 28 mm	Class IIa Q010507		2023-12-27
3528010B - Sendoline K-File 10 28 mm	Class IIa Q010507		2023-12-27
3528015B - Sendoline K-File 15 28 mm	Class IIa Q010507		2023-12-27
3528020B - Sendoline K-File 20 28 mm	Class IIa Q010507		2023-12-27
3528025B - Sendoline K-File 25 28 mm	Class IIa Q010507		2023-12-27
3528030B - Sendoline K-File 30 28 mm	Class IIa Q010507		2023-12-27
3528035B - Sendoline K-File 35 28 mm	Class IIa Q010507		2023-12-27
3528040B - Sendoline K-File 40 28 mm	Class IIa Q010507		2023-12-27
3528045B - Sendoline K-File 45 28 mm	Class IIa Q010507		2023-12-27
3528050B - Sendoline K-File 50 28 mm	Class IIa Q010507		2023-12-27
3528055B - Sendoline K-File 55 28 mm	Class IIa Q010507		2023-12-27
3528060B - Sendoline K-File 60 28 mm	Class IIa Q010507		2023-12-27
3528070B - Sendoline K-File 70 28 mm	Class IIa Q010507		2023-12-27
3528080B - Sendoline K-File 80 28 mm	Class IIa Q010507		2023-12-27
3528090B - Sendoline K-File 90 28 mm	Class IIa Q010507		2023-12-27
3528100B - Sendoline K-File 100 28 mm	Class IIa Q010507		2023-12-27
3528110B - Sendoline K-File 110 28 mm	Class IIa Q010507		2023-12-27
3528120B - Sendoline K-File 120 28 mm	Class IIa Q010507		2023-12-27
3528130B - Sendoline K-File 130 28 mm	Class IIa Q010507		2023-12-27
3528140B - Sendoline K-File 140 28 mm	Class IIa Q010507		2023-12-27
3531000B - Sendoline K-File Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
3531001B - Sendoline K-File Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
3531002B - Sendoline K-File Assorted 90-140 31 mm	Class IIa Q010507		2023-12-27
3531006B - Sendoline K-File 06 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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3531008B - Sendoline K-File 08 31 mm	Class IIa Q010507		2023-12-27
3531010B - Sendoline K-File 10 31 mm	Class IIa Q010507		2023-12-27
3531015B - Sendoline K-File 15 31 mm	Class IIa Q010507		2023-12-27
3531020B - Sendoline K-File 20 31 mm	Class IIa Q010507		2023-12-27
3531025B - Sendoline K-File 25 31 mm	Class IIa Q010507		2023-12-27
3531030B - Sendoline K-File 30 31 mm	Class IIa Q010507		2023-12-27
3531035B - Sendoline K-File 35 31 mm	Class IIa Q010507		2023-12-27
3531040B - Sendoline K-File 40 31 mm	Class IIa Q010507		2023-12-27
3531045B - Sendoline K-File 45 31 mm	Class IIa Q010507		2023-12-27
3531050B - Sendoline K-File 50 31 mm	Class IIa Q010507		2023-12-27
3531055B - Sendoline K-File 55 31 mm	Class IIa Q010507		2023-12-27
3531060B - Sendoline K-File 60 31 mm	Class IIa Q010507		2023-12-27
3531070B - Sendoline K-File 70 31 mm	Class IIa Q010507		2023-12-27
3531080B - Sendoline K-File 80 31 mm	Class IIa Q010507		2023-12-27
3531090B - Sendoline K-File 90 31 mm	Class IIa Q010507		2023-12-27
3531100B - Sendoline K-File 100 31 mm	Class IIa Q010507		2023-12-27
3531110B - Sendoline K-File 110 31 mm	Class IIa Q010507		2023-12-27
3531120B - Sendoline K-File 120 31 mm	Class IIa Q010507		2023-12-27
3531130B - Sendoline K-File 130 31 mm	Class IIa Q010507		2023-12-27
3531140B - Sendoline K-File 140 31 mm	Class IIa Q010507		2023-12-27
3621000B - Sendoline K-Reamer Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
3621001B - Sendoline K-Reamer Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
3621006B - Sendoline K-Reamer 06 21 mm	Class IIa Q010507		2023-12-27
3621008B - Sendoline K-Reamer 08 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3621010B - Sendoline K-Reamer 10 21 mm	Class IIa Q010507		2023-12-27
3621015B - Sendoline K-Reamer 15 21 mm	Class IIa Q010507		2023-12-27
3621020B - Sendoline K-Reamer 20 21 mm	Class IIa Q010507		2023-12-27
3621025B - Sendoline K-Reamer 25 21 mm	Class IIa Q010507		2023-12-27
3621030B - Sendoline K-Reamer 30 21 mm	Class IIa Q010507		2023-12-27
3621035B - Sendoline K-Reamer 35 21 mm	Class IIa Q010507		2023-12-27
3621040B - Sendoline K-Reamer 40 21 mm	Class IIa Q010507		2023-12-27
3621045B - Sendoline K-Reamer 45 21 mm	Class IIa Q010507		2023-12-27
3621050B - Sendoline K-Reamer 50 21 mm	Class IIa Q010507		2023-12-27
3621055B - Sendoline K-Reamer 55 21 mm	Class IIa Q010507		2023-12-27
3621060B - Sendoline K-Reamer 60 21 mm	Class IIa Q010507		2023-12-27
3621070B - Sendoline K-Reamer 70 21 mm	Class IIa Q010507		2023-12-27
3621080B - Sendoline K-Reamer 80 21 mm	Class IIa Q010507		2023-12-27
3621090B - Sendoline K-Reamer 90 21 mm	Class IIa Q010507		2023-12-27
3621100B - Sendoline K-Reamer 100 21 mm	Class IIa Q010507		2023-12-27
3621110B - Sendoline K-Reamer 110 21 mm	Class IIa Q010507		2023-12-27
3621120B - Sendoline K-Reamer 120 21 mm	Class IIa Q010507		2023-12-27
3621130B - Sendoline K-Reamer 130 21 mm	Class IIa Q010507		2023-12-27
3621140B - Sendoline K-Reamer 140 21 mm	Class IIa Q010507		2023-12-27
3625000B - Sendoline K-Reamer Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3625001B - Sendoline K-Reamer Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
3625006B - Sendoline K-Reamer 06 25 mm	Class IIa Q010507		2023-12-27
3625008B - Sendoline K-Reamer 08 25 mm	Class IIa Q010507		2023-12-27
3625010B - Sendoline K-Reamer 10 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3625015B - Sendoline K-Reamer 15 25 mm	Class IIa Q010507		2023-12-27
3625020B - Sendoline K-Reamer 20 25 mm	Class IIa Q010507		2023-12-27
3625025B - Sendoline K-Reamer 25 25 mm	Class IIa Q010507		2023-12-27
3625030B - Sendoline K-Reamer 30 25 mm	Class IIa Q010507		2023-12-27
3625035B - Sendoline K-Reamer 35 25 mm	Class IIa Q010507		2023-12-27
3625040B - Sendoline K-Reamer 40 25 mm	Class IIa Q010507		2023-12-27
3625045B - Sendoline K-Reamer 45 25 mm	Class IIa Q010507		2023-12-27
3625050B - Sendoline K-Reamer 50 25 mm	Class IIa Q010507		2023-12-27
3625055B - Sendoline K-Reamer 55 25 mm	Class IIa Q010507		2023-12-27
3625060B - Sendoline K-Reamer 60 25 mm	Class IIa Q010507		2023-12-27
3625070B - Sendoline K-Reamer 70 25 mm	Class IIa Q010507		2023-12-27
3625080B - Sendoline K-Reamer 80 25 mm	Class IIa Q010507		2023-12-27
3625090B - Sendoline K-Reamer 90 25 mm	Class IIa Q010507		2023-12-27
3625100B - Sendoline K-Reamer 100 25 mm	Class IIa Q010507		2023-12-27
3625110B - Sendoline K-Reamer 110 25 mm	Class IIa Q010507		2023-12-27
3625120B - Sendoline K-Reamer 120 25 mm	Class IIa Q010507		2023-12-27
3625130B - Sendoline K-Reamer 130 25 mm	Class IIa Q010507		2023-12-27
3625140B - Sendoline K-Reamer 140 25 mm	Class IIa Q010507		2023-12-27
3628000B - Sendoline K-Reamer Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
3628001B - Sendoline K-Reamer Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
3628006B - Sendoline K-Reamer 06 28 mm	Class IIa Q010507		2023-12-27
3628008B - Sendoline K-Reamer 08 28 mm	Class IIa Q010507		2023-12-27
3628010B - Sendoline K-Reamer 10 28 mm	Class IIa Q010507		2023-12-27
3628015B - Sendoline K-Reamer 15 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3628020B - Sendoline K-Reamer 20 28 mm	Class IIa Q010507		2023-12-27
3628025B - Sendoline K-Reamer 25 28 mm	Class IIa Q010507		2023-12-27
3628030B - Sendoline K-Reamer 30 28 mm	Class IIa Q010507		2023-12-27
3628035B - Sendoline K-Reamer 35 28 mm	Class IIa Q010507		2023-12-27
3628040B - Sendoline K-Reamer 40 28 mm	Class IIa Q010507		2023-12-27
3628045B - Sendoline K-Reamer 45 28 mm	Class IIa Q010507		2023-12-27
3628050B - Sendoline K-Reamer 50 28 mm	Class IIa Q010507		2023-12-27
3628055B - Sendoline K-Reamer 55 28 mm	Class IIa Q010507		2023-12-27
3628060B - Sendoline K-Reamer 60 28 mm	Class IIa Q010507		2023-12-27
3628070B - Sendoline K-Reamer 70 28 mm	Class IIa Q010507		2023-12-27
3628080B - Sendoline K-Reamer 80 28 mm	Class IIa Q010507		2023-12-27
3628090B - Sendoline K-Reamer 90 28 mm	Class IIa Q010507		2023-12-27
3628100B - Sendoline K-Reamer 100 28 mm	Class IIa Q010507		2023-12-27
3628110B - Sendoline K-Reamer 110 28 mm	Class IIa Q010507		2023-12-27
3628120B - Sendoline K-Reamer 120 28 mm	Class IIa Q010507		2023-12-27
3628130B - Sendoline K-Reamer 130 28 mm	Class IIa Q010507		2023-12-27
3628140B - Sendoline K-Reamer 140 28 mm	Class IIa Q010507		2023-12-27
3631000B - Sendoline K-Reamer Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
3631001B - Sendoline K-Reamer Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
3631006B - Sendoline K-Reamer 06 31 mm	Class IIa Q010507		2023-12-27
3631008B - Sendoline K-Reamer 08 31 mm	Class IIa Q010507		2023-12-27
3631010B - Sendoline K-Reamer 10 31 mm	Class IIa Q010507		2023-12-27
3631015B - Sendoline K-Reamer 15 31 mm	Class IIa Q010507		2023-12-27
3631020B - Sendoline K-Reamer 20 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3631025B - Sendoline K-Reamer 25 31 mm	Class IIa Q010507		2023-12-27
3631030B - Sendoline K-Reamer 30 31 mm	Class IIa Q010507		2023-12-27
3631035B - Sendoline K-Reamer 35 31 mm	Class IIa Q010507		2023-12-27
3631040B - Sendoline K-Reamer 40 31 mm	Class IIa Q010507		2023-12-27
3631045B - Sendoline K-Reamer 45 31 mm	Class IIa Q010507		2023-12-27
3631050B - Sendoline K-Reamer 50 31 mm	Class IIa Q010507		2023-12-27
3631055B - Sendoline K-Reamer 55 31 mm	Class IIa Q010507		2023-12-27
3631060B - Sendoline K-Reamer 60 31 mm	Class IIa Q010507		2023-12-27
3631070B - Sendoline K-Reamer 70 31 mm	Class IIa Q010507		2023-12-27
3631080B - Sendoline K-Reamer 80 31 mm	Class IIa Q010507		2023-12-27
3631090B - Sendoline K-Reamer 90 31 mm	Class IIa Q010507		2023-12-27
3631100B - Sendoline K-Reamer 100 31 mm	Class IIa Q010507		2023-12-27
3631110B - Sendoline K-Reamer 110 31 mm	Class IIa Q010507		2023-12-27
3631120B - Sendoline K-Reamer 120 31 mm	Class IIa Q010507		2023-12-27
3631130B - Sendoline K-Reamer 130 31 mm	Class IIa Q010507		2023-12-27
3631140B - Sendoline K-Reamer 140 31 mm	Class IIa Q010507		2023-12-27
3721000B - Sendoline S-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
3721001B - Sendoline S-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
3721002B - Sendoline S-File Assorted 90-140 21 mm	Class IIa Q010507		2023-12-27
3721006B - Sendoline S-File 06 21 mm	Class IIa Q010507		2023-12-27
3721008B - Sendoline S-File 08 21 mm	Class IIa Q010507		2023-12-27
3721010B - Sendoline S-File 10 21 mm	Class IIa Q010507		2023-12-27
3721015B - Sendoline S-File 15 21 mm	Class IIa Q010507		2023-12-27
3721020B - Sendoline S-File 20 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3721025B - Sendoline S-File 25 21 mm	Class IIa Q010507		2023-12-27
3721030B - Sendoline S-File 30 21 mm	Class IIa Q010507		2023-12-27
3721035B - Sendoline S-File 35 21 mm	Class IIa Q010507		2023-12-27
3721040B - Sendoline S-File 40 21 mm	Class IIa Q010507		2023-12-27
3721045B - Sendoline S-File 45 21 mm	Class IIa Q010507		2023-12-27
3721050B - Sendoline S-File 50 21 mm	Class IIa Q010507		2023-12-27
3721055B - Sendoline S-File 55 21 mm	Class IIa Q010507		2023-12-27
3721060B - Sendoline S-File 60 21 mm	Class IIa Q010507		2023-12-27
3721070B - Sendoline S-File 70 21 mm	Class IIa Q010507		2023-12-27
3721080B - Sendoline S-File 80 21 mm	Class IIa Q010507		2023-12-27
3721090B - Sendoline S-File 90 21 mm	Class IIa Q010507		2023-12-27
3721100B - Sendoline S-File 100 21 mm	Class IIa Q010507		2023-12-27
3721110B - Sendoline S-File 110 21 mm	Class IIa Q010507		2023-12-27
3721120B - Sendoline S-File 120 21 mm	Class IIa Q010507		2023-12-27
3721130B - Sendoline S-File 130 21 mm	Class IIa Q010507		2023-12-27
3721140B - Sendoline S-File 140 21 mm	Class IIa Q010507		2023-12-27
3725000B - Sendoline S-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
3725001B - Sendoline S-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
3725002B - Sendoline S-File Assorted 90-140 25 mm	Class IIa Q010507		2023-12-27
3725006B - Sendoline S-File 06 25 mm	Class IIa Q010507		2023-12-27
3725008B - Sendoline S-File 08 25 mm	Class IIa Q010507		2023-12-27
3725010B - Sendoline S-File 10 25 mm	Class IIa Q010507		2023-12-27
3725015B - Sendoline S-File 15 25 mm	Class IIa Q010507		2023-12-27
3725020B - Sendoline S-File 20 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3725025B - Sendoline S-File 25 25 mm	Class IIa Q010507		2023-12-27
3725030B - Sendoline S-File 30 25 mm	Class IIa Q010507		2023-12-27
3725035B - Sendoline S-File 35 25 mm	Class IIa Q010507		2023-12-27
3725040B - Sendoline S-File 40 25 mm	Class IIa Q010507		2023-12-27
3725045B - Sendoline S-File 45 25 mm	Class IIa Q010507		2023-12-27
3725050B - Sendoline S-File 50 25 mm	Class IIa Q010507		2023-12-27
3725055B - Sendoline S-File 55 25 mm	Class IIa Q010507		2023-12-27
3725060B - Sendoline S-File 60 25 mm	Class IIa Q010507		2023-12-27
3725070B - Sendoline S-File 70 25 mm	Class IIa Q010507		2023-12-27
3725080B - Sendoline S-File 80 25 mm	Class IIa Q010507		2023-12-27
3725090B - Sendoline S-File 90 25 mm	Class IIa Q010507		2023-12-27
3725100B - Sendoline S-File 100 25 mm	Class IIa Q010507		2023-12-27
3725110B - Sendoline S-File 110 25 mm	Class IIa Q010507		2023-12-27
3725120B - Sendoline S-File 120 25 mm	Class IIa Q010507		2023-12-27
3725130B - Sendoline S-File 130 25 mm	Class IIa Q010507		2023-12-27
3725140B - Sendoline S-File 140 25 mm	Class IIa Q010507		2023-12-27
3728000B - Sendoline S-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
3728001B - Sendoline S-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
3728002B - Sendoline S-File Assorted 90-140 28 mm	Class IIa Q010507		2023-12-27
3728006B - Sendoline S-File 06 28 mm	Class IIa Q010507		2023-12-27
3728008B - Sendoline S-File 08 28 mm	Class IIa Q010507		2023-12-27
3728010B - Sendoline S-File 10 28 mm	Class IIa Q010507		2023-12-27
3728015B - Sendoline S-File 15 28 mm	Class IIa Q010507		2023-12-27
3728020B - Sendoline S-File 20 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3728025B - Sendoline S-File 25 28 mm	Class IIa Q010507		2023-12-27
3728030B - Sendoline S-File 30 28 mm	Class IIa Q010507		2023-12-27
3728035B - Sendoline S-File 35 28 mm	Class IIa Q010507		2023-12-27
3728040B - Sendoline S-File 40 28 mm	Class IIa Q010507		2023-12-27
3728045B - Sendoline S-File 45 28 mm	Class IIa Q010507		2023-12-27
3728050B - Sendoline S-File 50 28 mm	Class IIa Q010507		2023-12-27
3728055B - Sendoline S-File 55 28 mm	Class IIa Q010507		2023-12-27
3728060B - Sendoline S-File 60 28 mm	Class IIa Q010507		2023-12-27
3728070B - Sendoline S-File 70 28 mm	Class IIa Q010507		2023-12-27
3728080B - Sendoline S-File 80 28 mm	Class IIa Q010507		2023-12-27
3728090B - Sendoline S-File 90 28 mm	Class IIa Q010507		2023-12-27
3728100B - Sendoline S-File 100 28 mm	Class IIa Q010507		2023-12-27
3728110B - Sendoline S-File 110 28 mm	Class IIa Q010507		2023-12-27
3728120B - Sendoline S-File 120 28 mm	Class IIa Q010507		2023-12-27
3728130B - Sendoline S-File 130 28 mm	Class IIa Q010507		2023-12-27
3728140B - Sendoline S-File 140 28 mm	Class IIa Q010507		2023-12-27
3731000B - Sendoline S-File Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
3731001B - Sendoline S-File Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
3731002B - Sendoline S-File Assorted 90-140 31 mm	Class IIa Q010507		2023-12-27
3731006B - Sendoline S-File 06 31 mm	Class IIa Q010507		2023-12-27
3731008B - Sendoline S-File 08 31 mm	Class IIa Q010507		2023-12-27
3731010B - Sendoline S-File 10 31 mm	Class IIa Q010507		2023-12-27
3731015B - Sendoline S-File 15 31 mm	Class IIa Q010507		2023-12-27
3731020B - Sendoline S-File 20 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
3731025B - Sendoline S-File 25 31 mm	Class IIa Q010507		2023-12-27
3731030B - Sendoline S-File 30 31 mm	Class IIa Q010507		2023-12-27
3731035B - Sendoline S-File 35 31 mm	Class IIa Q010507		2023-12-27
3731040B - Sendoline S-File 40 31 mm	Class IIa Q010507		2023-12-27
3731045B - Sendoline S-File 45 31 mm	Class IIa Q010507		2023-12-27
3731050B - Sendoline S-File 50 31 mm	Class IIa Q010507		2023-12-27
3731055B - Sendoline S-File 55 31 mm	Class IIa Q010507		2023-12-27
3731060B - Sendoline S-File 60 31 mm	Class IIa Q010507		2023-12-27
3731070B - Sendoline S-File 70 31 mm	Class IIa Q010507		2023-12-27
3731080B - Sendoline S-File 80 31 mm	Class IIa Q010507		2023-12-27
3731090B - Sendoline S-File 90 31 mm	Class IIa Q010507		2023-12-27
3731100B - Sendoline S-File 100 31 mm	Class IIa Q010507		2023-12-27
3731110B - Sendoline S-File 110 31 mm	Class IIa Q010507		2023-12-27
3731120B - Sendoline S-File 120 31 mm	Class IIa Q010507		2023-12-27
3731130B - Sendoline S-File 130 31 mm	Class IIa Q010507		2023-12-27
3731140B - Sendoline S-File 140 31 mm	Class IIa Q010507		2023-12-27
4221000B - Sendoline NiTi S-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
4221001B - Sendoline NiTi S-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
4221015B - Sendoline NiTi S-File 15 21 mm	Class IIa Q010507		2023-12-27
4221020B - Sendoline NiTi S-File 20 21 mm	Class IIa Q010507		2023-12-27
4221025B - Sendoline NiTi S-File 25 21 mm	Class IIa Q010507		2023-12-27
4221030B - Sendoline NiTi S-File 30 21 mm	Class IIa Q010507		2023-12-27
4221035B - Sendoline NiTi S-File 35 21 mm	Class IIa Q010507		2023-12-27
4221040B - Sendoline NiTi S-File 40 21 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4221045B - Sendoline NiTi S-File 45 21 mm	Class IIa Q010507		2023-12-27
4221050B - Sendoline NiTi S-File 50 21 mm	Class IIa Q010507		2023-12-27
4221055B - Sendoline NiTi S-File 55 21 mm	Class IIa Q010507		2023-12-27
4221060B - Sendoline NiTi S-File 60 21 mm	Class IIa Q010507		2023-12-27
4221070B - Sendoline NiTi S-File 70 21 mm	Class IIa Q010507		2023-12-27
4221080B - Sendoline NiTi S-File 80 21 mm	Class IIa Q010507		2023-12-27
4225000B - Sendoline NiTi S-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
4225001B - Sendoline NiTi S-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
4225015B - Sendoline NiTi S-File 15 25 mm	Class IIa Q010507		2023-12-27
4225020B - Sendoline NiTi S-File 20 25 mm	Class IIa Q010507		2023-12-27
4225025B - Sendoline NiTi S-File 25 25 mm	Class IIa Q010507		2023-12-27
4225030B - Sendoline NiTi S-File 30 25 mm	Class IIa Q010507		2023-12-27
4225035B - Sendoline NiTi S-File 35 25 mm	Class IIa Q010507		2023-12-27
4225040B - Sendoline NiTi S-File 40 25 mm	Class IIa Q010507		2023-12-27
4225045B - Sendoline NiTi S-File 45 25 mm	Class IIa Q010507		2023-12-27
4225050B - Sendoline NiTi S-File 50 25 mm	Class IIa Q010507		2023-12-27
4225055B - Sendoline NiTi S-File 55 25 mm	Class IIa Q010507		2023-12-27
4225060B - Sendoline NiTi S-File 60 25 mm	Class IIa Q010507		2023-12-27
4225070B - Sendoline NiTi S-File 70 25 mm	Class IIa Q010507		2023-12-27
4225080B - Sendoline NiTi S-File 80 25 mm	Class IIa Q010507		2023-12-27
4228000B - Sendoline NiTi S-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
4228001B - Sendoline NiTi S-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
4228015B - Sendoline NiTi S-File 15 28 mm	Class IIa Q010507		2023-12-27
4228020B - Sendoline NiTi S-File 20 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4228025B - Sendoline NiTi S-File 25 28 mm	Class IIa Q010507		2023-12-27
4228030B - Sendoline NiTi S-File 30 28 mm	Class IIa Q010507		2023-12-27
4228035B - Sendoline NiTi S-File 35 28 mm	Class IIa Q010507		2023-12-27
4228040B - Sendoline NiTi S-File 40 28 mm	Class IIa Q010507		2023-12-27
4228045B - Sendoline NiTi S-File 45 28 mm	Class IIa Q010507		2023-12-27
4228050B - Sendoline NiTi S-File 50 28 mm	Class IIa Q010507		2023-12-27
4228055B - Sendoline NiTi S-File 55 28 mm	Class IIa Q010507		2023-12-27
4228060B - Sendoline NiTi S-File 60 28 mm	Class IIa Q010507		2023-12-27
4228070B - Sendoline NiTi S-File 70 28 mm	Class IIa Q010507		2023-12-27
4228080B - Sendoline NiTi S-File 80 28 mm	Class IIa Q010507		2023-12-27
4231000B - Sendoline NiTi S-File Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
4231001B - Sendoline NiTi S-File Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
4231015B - Sendoline NiTi S-File 15 31 mm	Class IIa Q010507		2023-12-27
4231020B - Sendoline NiTi S-File 20 31 mm	Class IIa Q010507		2023-12-27
4231025B - Sendoline NiTi S-File 25 31 mm	Class IIa Q010507		2023-12-27
4231030B - Sendoline NiTi S-File 30 31 mm	Class IIa Q010507		2023-12-27
4231035B - Sendoline NiTi S-File 35 31 mm	Class IIa Q010507		2023-12-27
4231040B - Sendoline NiTi S-File 40 31 mm	Class IIa Q010507		2023-12-27
4231045B - Sendoline NiTi S-File 45 31 mm	Class IIa Q010507		2023-12-27
4231050B - Sendoline NiTi S-File 50 31 mm	Class IIa Q010507		2023-12-27
4231055B - Sendoline NiTi S-File 55 31 mm	Class IIa Q010507		2023-12-27
4231060B - Sendoline NiTi S-File 60 31 mm	Class IIa Q010507		2023-12-27
4231070B - Sendoline NiTi S-File 70 31 mm	Class IIa Q010507		2023-12-27
4231080B - Sendoline NiTi S-File 80 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4321000B - Sendoline NiTi H-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
4321001B - Sendoline NiTi H-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
4321015B - Sendoline NiTi H-File 15 21 mm	Class IIa Q010507		2023-12-27
4321020B - Sendoline NiTi H-File 20 21 mm	Class IIa Q010507		2023-12-27
4321025B - Sendoline NiTi H-File 25 21 mm	Class IIa Q010507		2023-12-27
4321030B - Sendoline NiTi H-File 30 21 mm	Class IIa Q010507		2023-12-27
4321035B - Sendoline NiTi H-File 35 21 mm	Class IIa Q010507		2023-12-27
4321040B - Sendoline NiTi H-File 40 21 mm	Class IIa Q010507		2023-12-27
4321045B - Sendoline NiTi H-File 45 21 mm	Class IIa Q010507		2023-12-27
4321050B - Sendoline NiTi H-File 50 21 mm	Class IIa Q010507		2023-12-27
4321055B - Sendoline NiTi H-File 55 21 mm	Class IIa Q010507		2023-12-27
4321060B - Sendoline NiTi H-File 60 21 mm	Class IIa Q010507		2023-12-27
4321070B - Sendoline NiTi H-File 70 21 mm	Class IIa Q010507		2023-12-27
4321080B - Sendoline NiTi H-File 80 21 mm	Class IIa Q010507		2023-12-27
4325000B - Sendoline NiTi H-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
4325001B - Sendoline NiTi H-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27
4325015B - Sendoline NiTi H-File 15 25 mm	Class IIa Q010507		2023-12-27
4325020B - Sendoline NiTi H-File 20 25 mm	Class IIa Q010507		2023-12-27
4325025B - Sendoline NiTi H-File 25 25 mm	Class IIa Q010507		2023-12-27
4325030B - Sendoline NiTi H-File 30 25 mm	Class IIa Q010507		2023-12-27
4325035B - Sendoline NiTi H-File 35 25 mm	Class IIa Q010507		2023-12-27
4325040B - Sendoline NiTi H-File 40 25 mm	Class IIa Q010507		2023-12-27
4325045B - Sendoline NiTi H-File 45 25 mm	Class IIa Q010507		2023-12-27
4325050B - Sendoline NiTi H-File 50 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4325055B - Sendoline NiTi H-File 55 25 mm	Class IIa Q010507		2023-12-27
4325060B - Sendoline NiTi H-File 60 25 mm	Class IIa Q010507		2023-12-27
4325070B - Sendoline NiTi H-File 70 25 mm	Class IIa Q010507		2023-12-27
4325080B - Sendoline NiTi H-File 80 25 mm	Class IIa Q010507		2023-12-27
4328000B - Sendoline NiTi H-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
4328001B - Sendoline NiTi H-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
4328015B - Sendoline NiTi H-File 15 28 mm	Class IIa Q010507		2023-12-27
4328020B - Sendoline NiTi H-File 20 28 mm	Class IIa Q010507		2023-12-27
4328025B - Sendoline NiTi H-File 25 28 mm	Class IIa Q010507		2023-12-27
4328030B - Sendoline NiTi H-File 30 28 mm	Class IIa Q010507		2023-12-27
4328035B - Sendoline NiTi H-File 35 28 mm	Class IIa Q010507		2023-12-27
4328040B - Sendoline NiTi H-File 40 28 mm	Class IIa Q010507		2023-12-27
4328045B - Sendoline NiTi H-File 45 28 mm	Class IIa Q010507		2023-12-27
4328050B - Sendoline NiTi H-File 50 28 mm	Class IIa Q010507		2023-12-27
4328055B - Sendoline NiTi H-File 55 28 mm	Class IIa Q010507		2023-12-27
4328060B - Sendoline NiTi H-File 60 28 mm	Class IIa Q010507		2023-12-27
4328070B - Sendoline NiTi H-File 70 28 mm	Class IIa Q010507		2023-12-27
4328080B - Sendoline NiTi H-File 80 28 mm	Class IIa Q010507		2023-12-27
4331000B - Sendoline NiTi H-File Assorted 15-40 31 mm	Class IIa Q010507		2023-12-27
4331001B - Sendoline NiTi H-File Assorted 45-80 31 mm	Class IIa Q010507		2023-12-27
4331015B - Sendoline NiTi H-File 15 31 mm	Class IIa Q010507		2023-12-27
4331020B - Sendoline NiTi H-File 20 31 mm	Class IIa Q010507		2023-12-27
4331025B - Sendoline NiTi H-File 25 31 mm	Class IIa Q010507		2023-12-27
4331030B - Sendoline NiTi H-File 30 31 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4331035B - Sendoline NiTi H-File 35 31 mm	Class IIa Q010507		2023-12-27
4331040B - Sendoline NiTi H-File 40 31 mm	Class IIa Q010507		2023-12-27
4331045B - Sendoline NiTi H-File 45 31 mm	Class IIa Q010507		2023-12-27
4331050B - Sendoline NiTi H-File 50 31 mm	Class IIa Q010507		2023-12-27
4331055B - Sendoline NiTi H-File 55 31 mm	Class IIa Q010507		2023-12-27
4331060B - Sendoline NiTi H-File 60 31 mm	Class IIa Q010507		2023-12-27
4331070B - Sendoline NiTi H-File 70 31 mm	Class IIa Q010507		2023-12-27
4331080B - Sendoline NiTi H-File 80 31 mm	Class IIa Q010507		2023-12-27
4521000B - Sendoline NiTi K-File Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
4521001B - Sendoline NiTi K-File Assorted 45-80 21 mm	Class IIa Q010507		2023-12-27
4521015B - Sendoline NiTi K-File 15 21 mm	Class IIa Q010507		2023-12-27
4521020B - Sendoline NiTi K-File 20 21 mm	Class IIa Q010507		2023-12-27
4521025B - Sendoline NiTi K-File 25 21 mm	Class IIa Q010507		2023-12-27
4521030B - Sendoline NiTi K-File 30 21 mm	Class IIa Q010507		2023-12-27
4521035B - Sendoline NiTi K-File 35 21 mm	Class IIa Q010507		2023-12-27
4521040B - Sendoline NiTi K-File 40 21 mm	Class IIa Q010507		2023-12-27
4521045B - Sendoline NiTi K-File 45 21 mm	Class IIa Q010507		2023-12-27
4521050B - Sendoline NiTi K-File 50 21 mm	Class IIa Q010507		2023-12-27
4521055B - Sendoline NiTi K-File 55 21 mm	Class IIa Q010507		2023-12-27
4521060B - Sendoline NiTi K-File 60 21 mm	Class IIa Q010507		2023-12-27
4521070B - Sendoline NiTi K-File 70 21 mm	Class IIa Q010507		2023-12-27
4521080B - Sendoline NiTi K-File 80 21 mm	Class IIa Q010507		2023-12-27
4525000B - Sendoline NiTi K-File Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
4525001B - Sendoline NiTi K-File Assorted 45-80 25 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4525015B - Sendoline NiTi K-File 15 25 mm	Class IIa Q010507		2023-12-27
4525020B - Sendoline NiTi K-File 20 25 mm	Class IIa Q010507		2023-12-27
4525025B - Sendoline NiTi K-File 25 25 mm	Class IIa Q010507		2023-12-27
4525030B - Sendoline NiTi K-File 30 25 mm	Class IIa Q010507		2023-12-27
4525035B - Sendoline NiTi K-File 35 25 mm	Class IIa Q010507		2023-12-27
4525040B - Sendoline NiTi K-File 40 25 mm	Class IIa Q010507		2023-12-27
4525045B - Sendoline NiTi K-File 45 25 mm	Class IIa Q010507		2023-12-27
4525050B - Sendoline NiTi K-File 50 25 mm	Class IIa Q010507		2023-12-27
4525055B - Sendoline NiTi K-File 55 25 mm	Class IIa Q010507		2023-12-27
4525060B - Sendoline NiTi K-File 60 25 mm	Class IIa Q010507		2023-12-27
4525070B - Sendoline NiTi K-File 70 25 mm	Class IIa Q010507		2023-12-27
4525080B - Sendoline NiTi K-File 80 25 mm	Class IIa Q010507		2023-12-27
4528000B - Sendoline NiTi K-File Assorted 15-40 28 mm	Class IIa Q010507		2023-12-27
4528001B - Sendoline NiTi K-File Assorted 45-80 28 mm	Class IIa Q010507		2023-12-27
4528015B - Sendoline NiTi K-File 15 28 mm	Class IIa Q010507		2023-12-27
4528020B - Sendoline NiTi K-File 20 28 mm	Class IIa Q010507		2023-12-27
4528025B - Sendoline NiTi K-File 25 28 mm	Class IIa Q010507		2023-12-27
4528030B - Sendoline NiTi K-File 30 28 mm	Class IIa Q010507		2023-12-27
4528035B - Sendoline NiTi K-File 35 28 mm	Class IIa Q010507		2023-12-27
4528040B - Sendoline NiTi K-File 40 28 mm	Class IIa Q010507		2023-12-27
4528045B - Sendoline NiTi K-File 45 28 mm	Class IIa Q010507		2023-12-27
4528050B - Sendoline NiTi K-File 50 28 mm	Class IIa Q010507		2023-12-27
4528055B - Sendoline NiTi K-File 55 28 mm	Class IIa Q010507		2023-12-27
4528060B - Sendoline NiTi K-File 60 28 mm	Class IIa Q010507		2023-12-27

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
4528070B - Sendoline NiTi K-File 70 28 mm	Class IIa Q010507		2023-12-27
4528080B - Sendoline NiTi K-File 80 28 mm	Class IIa Q010507		2023-12-27
4721000B - Sendoline NiTi K-Reamer Assorted 15-40 21 mm	Class IIa Q010507		2023-12-27
4721015B - Sendoline NiTi K-Reamer 15 21 mm	Class IIa Q010507		2023-12-27
4721020B - Sendoline NiTi K-Reamer 20 21 mm	Class IIa Q010507		2023-12-27
4721025B - Sendoline NiTi K-Reamer 25 21 mm	Class IIa Q010507		2023-12-27
4721030B - Sendoline NiTi K-Reamer 30 21 mm	Class IIa Q010507		2023-12-27
4721035B - Sendoline NiTi K-Reamer 35 21 mm	Class IIa Q010507		2023-12-27
4721040B - Sendoline NiTi K-Reamer 40 21 mm	Class IIa Q010507		2023-12-27
4725000B - Sendoline NiTi K-Reamer Assorted 15-40 25 mm	Class IIa Q010507		2023-12-27
4725015B - Sendoline NiTi K-Reamer 15 25 mm	Class IIa Q010507		2023-12-27
4725020B - Sendoline NiTi K-Reamer 20 25 mm	Class IIa Q010507		2023-12-27
4725025B - Sendoline NiTi K-Reamer 25 25 mm	Class IIa Q010507		2023-12-27
4725030B - Sendoline NiTi K-Reamer 30 25 mm	Class IIa Q010507		2023-12-27
4725035B - Sendoline NiTi K-Reamer 35 25 mm	Class IIa Q010507		2023-12-27
4725040B - Sendoline NiTi K-Reamer 40 25 mm	Class IIa Q010507		2023-12-27


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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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