EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 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 Regulation (EU) 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.

MPS Micro Precision Systems AG

Chemin du Long-Champ 95, Biel-Bienne, 2504, Switzerland

Manufacturer SRN: CH-MF-000032439

Authorised Representative Name

Emergo Europe B.V

Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands

Scope:

Orthopaedic instruments

Certificate Number:
28620145896

Revision:
01

Initial Certification Date:
30 March 2023

Certificate Decision Date:
28 June 2023

Certificate Issue Date:
28 June 2023

Certificate Expiry Date:
29 March 2028

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

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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Audit Report Reference	**CN00143-04**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620145896	30 March 2023	Initial Certificate

Mikael Hagelin
Certification Authority, MDR
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PRODUCT LIST FOR CERTIFICATE

Issued to: MPS Micro Precision Systems AG

Certificate number: 28620145896-01

Certificate valid from: 2023-06-28

Product list issue date:
05 October 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Orthopaedic instruments			
Basic UDI-DI: 764018791DRILLAO01MC			
T14935 - Drill little AO coupling Ø2.5 x 180 mm	Class IIa Z12130503		2024-03-26
T835 - Drill little AO coupling Ø3.5 x 195 mm	Class IIa Z12130503		2024-03-26
T878 - Drill little AO coupling Ø3.2 x 145 mm	Class IIa Z12130503		2024-03-26
T880 - Drill little AO coupling Ø4.5 x 145 mm	Class IIa Z12130503		2024-03-26
T882 - Drill little AO coupling Ø3.5 x 110 mm	Class IIa Z12130503		2024-03-26
T883 - Drill little AO coupling Ø3.5 x 145 mm	Class IIa Z12130503		2024-03-26
Basic UDI-DI: 764018791DRILLBAYONET01UW			
T10154 - Bayonet drill Ø3.2 x 42 mm	Class IIa Z12130503		2024-03-26
T10476 - Bayonet drill Ø3.2 x 62 mm	Class IIa Z12130503		2024-03-26
T12481 - Bayonet drill Ø4.5 x 35 mm	Class IIa Z12130503		2024-03-26
T1262 - Bayonet drill Ø4.5 x 70 mm	Class IIa Z12130503		2024-03-26
T15607 - Bayonet drill Ø4.5 x 42 mm	Class IIa Z12130503		2024-03-26
T17972 - Bayonet drill Ø3.8 x 40 mm	Class IIa Z12130503		2024-03-26

[1]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[1]	Date Added
T2282 - Bayonet drill Ø4.5 x 50 mm	Class IIa Z12130503		2024-03-26
T2287 - Bayonet drill Ø4.5 x 62 mm	Class IIa Z12130503		2024-03-26
T2288 - Bayonet drill Ø3.2 x 52 mm	Class IIa Z12130503		2024-03-26
T2313 - Bayonet drill Ø3.2 x 62 mm	Class IIa Z12130503		2024-03-26
T2314 - Bayonet drill Ø3.2 x 42 mm	Class IIa Z12130503		2024-03-26
T3163 - Bayonet drill Ø3.5 x 35 mm	Class IIa Z12130503		2024-03-26
T3313 - Bayonet drill Ø4.5 x 56 mm	Class IIa Z12130503		2024-03-26
T6028 - Bayonet drill Ø3.2 x 40 mm	Class IIa Z12130503		2024-03-26
T6029 - Bayonet drill Ø3.2 x 59 mm	Class IIa Z12130503		2024-03-26
T716 - Bayonet drill Ø3.2 x 50 mm	Class IIa Z12130503		2024-03-26
T717 - Bayonet drill Ø3.2 x 70 mm	Class IIa Z12130503		2024-03-26
T718 - Bayonet drill Ø3.5 x 50 mm	Class IIa Z12130503		2024-03-26
T830 - Bayonet drill Ø3.2 x 56 mm	Class IIa Z12130503		2024-03-26
Basic UDI-DI: 764018791DRILLSTR01LZ			
T4582 - Drill Ø1.5 x 70 mm	Class IIa Z12130503		2024-03-26
T827 - Drill Ø3.2 x 146 mm	Class IIa Z12130503		2024-03-26
Basic UDI-DI: 764018791IMREAMENTRY01M2			
T18772 - TRIGEN MAX ENTRY REAMER 12.5 MM, HALL-JACOBS	Class IIa L091102		2025-06-30
Basic UDI-DI: 764018791IMREAMHEAD013G			
T10304 - IM reamer head dove tail Ø20.5 x 35 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29

[1]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[1]	Date Added
T10305 - IM reamer head dove tail Ø21.5 x 36 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T10306 - IM reamer head dove tail Ø22.5 x 37 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T10307 - IM reamer head dove tail Ø23 x 38 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T10308 - IM reamer head dove tail Ø23.5 x 38 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T10309 - IM reamer head dove tail Ø24 x 39 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T14434 - IM reamer head dove tail Ø9 x 21 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14435 - IM reamer head dove tail Ø9.5 x 22 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14436 - IM reamer head dove tail Ø10 x 23 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14437 - IM reamer head dove tail Ø10.5 x 23 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14438 - IM reamer head dove tail Ø11 x 24 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14439 - IM reamer head dove tail Ø11.5 x 25 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14440 - IM reamer head dove tail Ø12 x 25 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14441 - IM reamer head dove tail Ø12.5 x 26 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T14442 - IM reamer head dove tail Ø13 x 27 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14443 - IM reamer head dove tail Ø13.5 x 27 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14444 - IM reamer head dove tail Ø14 x 28 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14445 - IM reamer head dove tail Ø14.5 x 28 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14446 - IM reamer head dove tail Ø15 x 29 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14447 - IM reamer head dove tail Ø15.5 x 29 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14448 - IM reamer head dove tail Ø16 x 30 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14449 - IM reamer head dove tail Ø16.5 x 31 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14450 - IM reamer head dove tail Ø17 x 31 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14451 - IM reamer head dove tail Ø 17.5 x 32 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14452 - IM reamer head dove tail Ø18 x 32 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14453 - IM reamer head dove tail Ø18.5 x 33 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T14454 - IM reamer head dove tail Ø19 x 33 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T14455 - IM reamer head dove tail Ø19.5 x 34 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2024-03-26
T16168 - IM reamer head dove tail Ø9 x 21 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16169 - IM reamer head dove tail Ø9.5 x 22 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16170 - IM reamer head dove tail Ø10 x 23 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16171 - IM reamer head dove tail Ø10.5 x 23 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16172 - IM reamer head dove tail Ø11 x 24 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16173 - IM reamer head dove tail Ø11.5 x 25 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16174 - IM reamer head dove tail Ø12 x 25 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16175 - IM reamer head dove tail Ø12.5 x 26 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16176 - IM reamer head dove tail Ø13 x 27 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16177 - IM reamer head dove tail Ø13.5 x 27 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16178 - IM reamer head dove tail Ø14 x 28 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16179 - IM reamer head dove tail Ø14.5 x 28 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T16180 - IM reamer head dove tail Ø15 x 29 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16181 - IM reamer head dove tail Ø15.5 x 29 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16182 - IM reamer head dove tail Ø16 x 30 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16183 - IM reamer head dove tail Ø16.5 x 31 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16184 - IM reamer head dove tail Ø17 x 31 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16185 - IM reamer head dove tail Ø17.5 x 32 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16186 - IM reamer head dove tail Ø18 x 32 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16187 - IM reamer head dove tail Ø18.5 x 33 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16188 - IM reamer head dove tail Ø19 x 33 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16189 - IM reamer head dove tail Ø19.5 x 34 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16190 - IM reamer head dove tail Ø20 x 34 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T16191 - IM reamer head dove tail Ø20.5 x 35 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16192 - IM reamer head dove tail Ø21 x 35 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29

[1]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[1]	Date Added
T16193 - IM reamer head dove tail Ø21.5 x 36 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16194 - IM reamer head dove tail Ø22 x 36 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16195 - IM reamer head dove tail Ø22.5 x 37 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16196 - IM reamer head dove tail Ø23 x 38 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16197 - IM reamer head dove tail Ø23.5 x 38 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T16198 - IM reamer head dove tail Ø24 x 39 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T18365 - IM reamer head dove tail Ø9 x 21 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18366 - IM reamer head dove tail Ø9.5 x 22 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18367 - IM reamer head dove tail Ø10 x 23 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18368 - IM reamer head dove tail Ø10.5 x 23 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18369 - IM reamer head dove tail Ø11 x 24 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18370 - IM reamer head dove tail Ø11.5 x 25 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18371 - IM reamer head dove tail Ø12 x 25 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T18372 - IM reamer head dove tail Ø12.5 x 26 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18373 - IM reamer head dove tail Ø13 x 27 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18374 - IM reamer head dove tail Ø13.5 x 27 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18375 - IM reamer head dove tail Ø14 x 28 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18376 - IM reamer head dove tail Ø14.5 x 28 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18377 - IM reamer head dove tail Ø15 x 29 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18378 - IM reamer head dove tail Ø15.5 x 29 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18379 - IM reamer head dove tail Ø16 x 30 mm, can. Ø3.1 mm with TiN coating	Class IIa L091102		2024-03-26
T18756 - TRIGEN MAX IM REAMER HEAD 8 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18757 - TRIGEN MAX IM REAMER HEAD 8.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18758 - TRIGEN MAX IM REAMER HEAD 9 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18759 - TRIGEN MAX IM REAMER HEAD 9.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18760 - TRIGEN MAX IM REAMER HEAD 10 MM, FRONT CUTTING	Class IIa L091102		2025-06-30

[1]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[1]	Date Added
T18761 - TRIGEN MAX IM REAMER HEAD 10.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18762 - TRIGEN MAX IM REAMER HEAD 11 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18763 - TRIGEN MAX IM REAMER HEAD 11.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18764 - TRIGEN MAX IM REAMER HEAD 12 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18765 - TRIGEN MAX IM REAMER HEAD 12.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18766 - TRIGEN MAX IM REAMER HEAD 13 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18767 - TRIGEN MAX IM REAMER HEAD 13.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18768 - TRIGEN MAX IM REAMER HEAD 14 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18769 - TRIGEN MAX IM REAMER HEAD 14.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18770 - TRIGEN MAX IM REAMER HEAD 15 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18774 - TRIGEN MAX IM REAMER HEAD 15.5 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18775 - TRIGEN MAX IM REAMER HEAD 16 MM, FRONT CUTTING	Class IIa L091102		2025-06-30
T18882 - QuickSwitch IMR Head Ø9 x 21 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18883 - QuickSwitch IMR Head Ø9.5 x 22 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18884 - QuickSwitch IMR Head Ø10 x 23 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18885 - QuickSwitch IMR Head Ø10.5 x 23 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05

[1]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[1]	Date Added
T18886 - QuickSwitch IMR Head Ø11 x 24 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18887 - QuickSwitch IMR Head Ø11.5 x 25 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18888 - QuickSwitch IMR Head Ø12 x 25 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18889 - QuickSwitch IMR Head Ø12.5 x 26 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18890 - QuickSwitch IMR Head Ø13 x 27 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18891 - QuickSwitch IMR Head Ø13.5 x 27 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18892 - QuickSwitch IMR Head Ø14 x 28 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18893 - QuickSwitch IMR Head Ø14.5 x 28 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18894 - QuickSwitch IMR Head Ø15 x 29 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18895 - QuickSwitch IMR Head Ø15.5 x 29 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18896 - QuickSwitch IMR Head Ø16 x 30 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18897 - QuickSwitch IMR Head Ø16.5 x 31 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18898 - QuickSwitch IMR Head Ø17 x 31 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18899 - QuickSwitch IMR Head Ø17.5 x 32 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18900 - QuickSwitch IMR Head Ø18 x 32 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18901 - QuickSwitch IMR Head Ø18.5 x 33 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18902 - QuickSwitch IMR Head Ø19 x 33 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18903 - QuickSwitch IMR Head Ø19.5 x 34 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18904 - QuickSwitch IMR Head ø20 x 34 mm, can. Ø3.4 mm	Class IIa L091102		2026-10-05
T18906 - IM reamer head dove tail Ø20 x 34 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29

[1]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[1]	Date Added
T18907 - IM reamer head dove tail Ø20.5 x 35 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18908 - IM reamer head dove tail Ø21 x 35 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18909 - IM reamer head dove tail Ø21.5 x 36 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18910 - IM reamer head dove tail Ø22 x 36 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18911 - IM reamer head dove tail Ø22.5 x 37 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18912 - IM reamer head dove tail Ø23 x 38 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18913 - IM reamer head dove tail Ø23.5 x 38 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T18914 - IM reamer head dove tail Ø24 x 39 mm, can. Ø3.4 mm without TiN coating	Class IIa L091102		2026-01-29
T3292 - IM reamer head dove tail Ø9 x 21 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3293 - IM reamer head dove tail Ø9.5 x 22 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3294 - IM reamer head dove tail Ø10 x 23 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3295 - IM reamer head dove tail Ø10.5 x 23 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3296 - IM reamer head dove tail Ø11 x 24 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T3297 - IM reamer head dove tail Ø11.5 x 25 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3298 - IM reamer head dove tail Ø12 x 25 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3299 - IM reamer head dove tail Ø12.5 x 26 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3300 - IM reamer head dove tail Ø13 x 27 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3301 - IM reamer head dove tail Ø13.5 x 27 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3302 - IM reamer head dove tail Ø14 x 28 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3303 - IM reamer head dove tail Ø14.5 x 28 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3304 - IM reamer head dove tail Ø15 x 29 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3305 - IM reamer head dove tail Ø15.5 x 29 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3306 - IM reamer head dove tail Ø16 x 30 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3307 - IM reamer head dove tail Ø16.5 x 31 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3308 - IM reamer head dove tail Ø17 x 31 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3309 - IM reamer head dove tail Ø17.5 x 32 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3416 - IM reamer head dove tail Ø18 x 32 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T3417 - IM reamer head dove tail Ø18.5 x 33 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3418 - IM reamer head dove tail Ø19 x 33 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3419 - IM reamer head dove tail Ø19.5 x 34 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3420 - IM reamer head dove tail Ø20 x 34 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2024-03-26
T3422 - IM reamer head dove tail Ø21 x 35 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
T3424 - IM reamer head dove tail Ø22 x 36 mm, can. Ø3.4 mm with TiN coating	Class IIa L091102		2026-01-29
Basic UDI-DI: 764018791IMREAMMONO01DH			
T116875 - Humeral IM reamer Ø6 x 341 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12046 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12047 - Femoral IM reamer Ø9.5 x 477 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12048 - Femoral IM reamer Ø10 x 477 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12049 - Femoral IM reamer Ø10.5 x 478 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12050 - Femoral IM reamer Ø11 x 478 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12051 - Femoral IM reamer Ø11.5 x 480 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12052 - Femoral IM reamer Ø12 x 480 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T12053 - Femoral IM reamer Ø12.5 x 480 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12054 - Femoral IM reamer Ø13 x 482 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T12055 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12056 - Femoral IM reamer Ø9.5 x 477 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12057 - Femoral IM reamer Ø10 x 477 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12058 - Femoral IM reamer Ø10.5 x 478 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12059 - Femoral IM reamer Ø11 x 478 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12060 - Femoral IM reamer Ø11.5 x 480 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12061 - Femoral IM reamer Ø12 x 480 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12062 - Femoral IM reamer Ø12.5 x 480 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12063 - Femoral IM reamer Ø13 x 482 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T12064 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12065 - Femoral IM reamer Ø9.5 x 477 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12066 - Femoral IM reamer Ø10 x 477 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T12067 - Femoral IM reamer Ø10.5 x 478 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12068 - Femoral IM reamer Ø11 x 478 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12069 - Femoral IM reamer Ø11.5 x 480 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12070 - Femoral IM reamer Ø12 x 480 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12071 - Femoral IM reamer Ø12.5 x 480 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T12072 - Femoral IM reamer Ø13 x 482 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T13669 - Humeral IM reamer Ø6 x 341 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30
T13670 - Humeral IM reamer Ø6.5 x 341 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30
T13671 - Humeral IM reamer Ø7 x 343 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30
T13672 - Humeral IM reamer Ø7.5 x 343 mm, can. Ø2.3 mm Hudson coup	Class IIa L091102		2025-06-30
T14038 - Humeral IM reamer Ø8 x 345 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30
T14039 - Humeral IM reamer Ø8.5 x 345 mm, can. Ø2.3 mm Hudson coup	Class IIa L091102		2025-06-30
T14040 - Humeral IM reamer Ø9 x 347 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30
T14041 - Humeral IM reamer Ø9.5 x 347 mm, can. Ø2.3 mm Hudson coup.	Class IIa L091102		2025-06-30

[1]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[1]	Date Added
T15123 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18137 - Femoral IM reamer Ø7 x 474 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18138 - Femoral IM reamer Ø7.5 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18139 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18140 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18141 - Femoral IM reamer Ø13.5 x 482 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18142 - Femoral IM reamer Ø14 x 482 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18143 - Femoral IM reamer Ø14.5 x 483 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18144 - Femoral IM reamer Ø15 x 483 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18149 - Femoral IM reamer Ø15.5 x 483 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18150 - Femoral IM reamer Ø16 x 483 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T18151 - Femoral IM reamer Ø7 x 474 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18152 - Femoral IM reamer Ø7.5 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18153 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T18154 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18155 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18156 - Femoral IM reamer Ø13.5 x 482 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18157 - Femoral IM reamer Ø14 x 482 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18158 - Femoral IM reamer Ø14.5 x 483 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18159 - Femoral IM reamer Ø15 x 483 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18160 - Femoral IM reamer Ø15.5 x 483 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18161 - Femoral IM reamer Ø16 x 483 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T18187 - Femoral IM reamer Ø7 x 474 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18188 - Femoral IM reamer Ø7.5 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18189 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18190 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18191 - Femoral IM reamer Ø9 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18192 - Femoral IM reamer Ø13.5 x 482 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T18193 - Femoral IM reamer Ø14 x 482 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18194 - Femoral IM reamer Ø14.5 x 483 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18195 - Femoral IM reamer Ø15 x 483 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18196 - Femoral IM reamer Ø15.5 x 483 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T18197 - Femoral IM reamer Ø16 x 483 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T4866 - Humeral IM reamer Ø6 x 341 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4867 - Humeral IM reamer Ø6.5 x 341 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4868 - Humeral IM reamer Ø7 x 343 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4869 - Humeral IM reamer Ø7.5 x 343 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4870 - Humeral IM reamer Ø8 x 345 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4871 - Humeral IM reamer Ø8.5 x 345 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T4872 - Humeral IM reamer Ø9 x 347 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T5357 - Humeral IM reamer Ø9.5 x 347 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T5358 - Humeral IM reamer Ø10 x 348 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T5359 - Humeral IM reamer Ø10.5 x 349 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T5360 - Humeral IM reamer Ø11 x 350 mm, can. Ø2.3 mm, Big AO coup.	Class IIa L091102		2024-03-26
T6410 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T6411 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Big AO coup.	Class IIa L091102		2024-03-26
T6412 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T6413 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Hudson coup.	Class IIa L091102		2024-03-26
T7552 - Femoral IM reamer Ø8 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7553 - Femoral IM reamer Ø8.5 x 475 mm, can. Ø3.1 mm Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7641 - Humeral IM reamer Ø6 x 341 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7642 - Humeral IM reamer Ø6.5 x 341 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7643 - Humeral IM reamer Ø7 x 343 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7644 - Humeral IM reamer Ø7.5 x 343 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7645 - Humeral IM reamer Ø8 x 345 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7646 - Humeral IM reamer Ø8.5 x 345 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26

[1]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[1]	Date Added
T7647 - Humeral IM reamer Ø9 x 347 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7648 - Humeral IM reamer Ø9.5 x 347 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7649 - Humeral IM reamer Ø10 x 348 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7650 - Humeral IM reamer Ø10.5 x 349 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
T7651 - Humeral IM reamer Ø11 x 350 mm, can. Ø2.3 mm, Stryker/Zimmer-Hall coup.	Class IIa L091102		2024-03-26
Basic UDI-DI: 764018791IMREAMSHAFT01G4			
T18162 - IM reamer extension 150 mm, dove tail	Class IIa Z12130580		2024-03-26
T18771 - TRIGEN MAX IM REAMER SHAFT 570 MM, HALL-JACOBS	Class IIa Z12130580		2025-06-30
T3444 - IM reamer shaft dove tail 470 mm, Big AO coup.	Class IIa Z12130580		2024-03-26
T3445 - IM reamer shaft dove tail 470 mm, Stryker/Zimmer-Hall coup.	Class IIa Z12130580		2024-03-26
T3713 - IM reamer shaft dove tail 470 mm, Hudson coup.	Class IIa Z12130580		2024-03-26
Basic UDI-DI: 764018791REAMACETAB01SP			
T13481 - Acetabular reamer Ø48 with round tooth	Class IIa L091102		2025-04-10
T13482 - Acetabular reamer Ø50 with round tooth	Class IIa L091102		2025-04-10
T13483 - Acetabular reamer Ø52 with round tooth	Class IIa L091102		2025-04-10
T13484 - Acetabular reamer Ø54 with round tooth	Class IIa L091102		2025-04-10
T13485 - Acetabular reamer Ø56 with round tooth	Class IIa L091102		2025-04-10
T13486 - Acetabular reamer Ø58 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T13487 - Acetabular reamer Ø60 with round tooth	Class IIa L091102		2025-04-10
T13488 - Acetabular reamer Ø62 with round tooth	Class IIa L091102		2025-04-10
T13489 - Acetabular reamer Ø64 with round tooth	Class IIa L091102		2025-04-10
T13490 - Acetabular reamer Ø66 with round tooth	Class IIa L091102		2025-04-10
T13491 - Acetabular reamer Ø68 with round tooth	Class IIa L091102		2025-04-10
T13492 - Acetabular reamer Ø70 with round tooth	Class IIa L091102		2025-04-10
T13493 - Acetabular reamer Ø72 with round tooth	Class IIa L091102		2025-04-10
T13494 - Acetabular reamer Ø74 with round tooth	Class IIa L091102		2025-04-10
T13495 - Acetabular reamer Ø76 with round tooth	Class IIa L091102		2025-04-10
T13726 - Acetabular reamer Ø38 with round tooth	Class IIa L091102		2025-04-10
T13727 - Acetabular reamer Ø39 with round tooth	Class IIa L091102		2025-04-10
T13728 - Acetabular reamer Ø40 with round tooth	Class IIa L091102		2025-04-10
T13729 - Acetabular reamer Ø41 with round tooth	Class IIa L091102		2025-04-10
T13730 - Acetabular reamer Ø42 with round tooth	Class IIa L091102		2025-04-10
T13731 - Acetabular reamer Ø43 with round tooth	Class IIa L091102		2025-04-10
T13732 - Acetabular reamer Ø44 with round tooth	Class IIa L091102		2025-04-10
T13733 - Acetabular reamer Ø45 with round tooth	Class IIa L091102		2025-04-10
T13734 - Acetabular reamer Ø46 with round tooth	Class IIa L091102		2025-04-10
T13735 - Acetabular reamer Ø47 with round tooth	Class IIa L091102		2025-04-10
T13736 - Acetabular reamer Ø49 with round tooth	Class IIa L091102		2025-04-10
T13737 - Acetabular reamer Ø51 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T13738 - Acetabular reamer Ø53 with round tooth	Class IIa L091102		2025-04-10
T13739 - Acetabular reamer Ø55 with round tooth	Class IIa L091102		2025-04-10
T13740 - Acetabular reamer Ø57 with round tooth	Class IIa L091102		2025-04-10
T15467 - Acetabular reamer Ø36 with round tooth	Class IIa L091102		2025-04-10
T15468 - Acetabular reamer Ø37 with round tooth	Class IIa L091102		2025-04-10
T15469 - Acetabular reamer Ø38 with round tooth	Class IIa L091102		2025-04-10
T15470 - Acetabular reamer Ø39 with round tooth	Class IIa L091102		2025-04-10
T15471 - Acetabular reamer Ø40 with round tooth	Class IIa L091102		2025-04-10
T15472 - Acetabular reamer Ø41 with round tooth	Class IIa L091102		2025-04-10
T15473 - Acetabular reamer Ø42 with round tooth	Class IIa L091102		2025-04-10
T15474 - Acetabular reamer Ø43 with round tooth	Class IIa L091102		2025-04-10
T15475 - Acetabular reamer Ø44 with round tooth	Class IIa L091102		2025-04-10
T15476 - Acetabular reamer Ø45 with round tooth	Class IIa L091102		2025-04-10
T15477 - Acetabular reamer Ø46 with round tooth	Class IIa L091102		2025-04-10
T15478 - Acetabular reamer Ø47 with round tooth	Class IIa L091102		2025-04-10
T15479 - Acetabular reamer Ø48 with round tooth	Class IIa L091102		2025-04-10
T15480 - Acetabular reamer Ø49 with round tooth	Class IIa L091102		2025-04-10
T15481 - Acetabular reamer Ø50 with round tooth	Class IIa L091102		2025-04-10
T15482 - Acetabular reamer Ø51 with round tooth	Class IIa L091102		2025-04-10
T15483 - Acetabular reamer Ø52 with round tooth	Class IIa L091102		2025-04-10
T15484 - Acetabular reamer Ø53 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T15485 - Acetabular reamer Ø54 with round tooth	Class IIa L091102		2025-04-10
T15486 - Acetabular reamer Ø55 with round tooth	Class IIa L091102		2025-04-10
T15487 - Acetabular reamer Ø56 with round tooth	Class IIa L091102		2025-04-10
T15488 - Acetabular reamer Ø57 with round tooth	Class IIa L091102		2025-04-10
T15489 - Acetabular reamer Ø58 with round tooth	Class IIa L091102		2025-04-10
T15490 - Acetabular reamer Ø59 with round tooth	Class IIa L091102		2025-04-10
T15491 - Acetabular reamer Ø60 with round tooth	Class IIa L091102		2025-04-10
T15492 - Acetabular reamer Ø61 with round tooth	Class IIa L091102		2025-04-10
T15493 - Acetabular reamer Ø62 with round tooth	Class IIa L091102		2025-04-10
T15494 - Acetabular reamer Ø63 with round tooth	Class IIa L091102		2025-04-10
T15495 - Acetabular reamer Ø64 with round tooth	Class IIa L091102		2025-04-10
T15496 - Acetabular reamer Ø65 with round tooth	Class IIa L091102		2025-04-10
T15497 - Acetabular reamer Ø66 with round tooth	Class IIa L091102		2025-04-10
T15498 - Acetabular reamer Ø67 with round tooth	Class IIa L091102		2025-04-10
T15499 - Acetabular reamer Ø68 with round tooth	Class IIa L091102		2025-04-10
T15500 - Acetabular reamer Ø69 with round tooth	Class IIa L091102		2025-04-10
T15501 - Acetabular reamer Ø70 with round tooth	Class IIa L091102		2025-04-10
T15502 - Acetabular reamer Ø71 with round tooth	Class IIa L091102		2025-04-10
T15503 - Acetabular reamer Ø72 with round tooth	Class IIa L091102		2025-04-10
T15504 - Acetabular reamer Ø73 with round tooth	Class IIa L091102		2025-04-10
T15505 - Acetabular reamer Ø74 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T15506 - Acetabular reamer Ø75 with round tooth	Class IIa L091102		2025-04-10
T15507 - Acetabular reamer Ø76 with round tooth	Class IIa L091102		2025-04-10
T15508 - Acetabular reamer Ø77 with round tooth	Class IIa L091102		2025-04-10
T15509 - Acetabular reamer Ø78 with round tooth	Class IIa L091102		2025-04-10
T15510 - Acetabular reamer Ø79 with round tooth	Class IIa L091102		2025-04-10
T15511 - Acetabular reamer Ø80 with round tooth	Class IIa L091102		2025-04-10
T16217 - Acetabular reamer Ø36 with round tooth	Class IIa L091102		2025-04-10
T16218 - Acetabular reamer Ø37 with round tooth	Class IIa L091102		2025-04-10
T16219 - Acetabular reamer Ø59 with round tooth	Class IIa L091102		2025-04-10
T16220 - Acetabular reamer Ø61 with round tooth	Class IIa L091102		2025-04-10
T16221 - Acetabular reamer Ø63 with round tooth	Class IIa L091102		2025-04-10
T16222 - Acetabular reamer Ø65 with round tooth	Class IIa L091102		2025-04-10
T16223 - Acetabular reamer Ø67 with round tooth	Class IIa L091102		2025-04-10
T16224 - Acetabular reamer Ø69 with round tooth	Class IIa L091102		2025-04-10
T16225 - Acetabular reamer Ø71 with round tooth	Class IIa L091102		2025-04-10
T16226 - Acetabular reamer Ø73 with round tooth	Class IIa L091102		2025-04-10
T16227 - Acetabular reamer Ø75 with round tooth	Class IIa L091102		2025-04-10
T16228 - Acetabular reamer Ø77 with round tooth	Class IIa L091102		2025-04-10
T16229 - Acetabular reamer Ø78 with round tooth	Class IIa L091102		2025-04-10
T16230 - Acetabular reamer Ø79 with round tooth	Class IIa L091102		2025-04-10
T16231 - Acetabular reamer Ø80 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T17793 - Acetabular reamer Ø36 with round tooth	Class IIa L091102		2025-04-10
T17794 - Acetabular reamer Ø37 with round tooth	Class IIa L091102		2025-04-10
T17795 - Acetabular reamer Ø38 with round tooth	Class IIa L091102		2025-04-10
T17796 - Acetabular reamer Ø39 with round tooth	Class IIa L091102		2025-04-10
T17797 - Acetabular reamer Ø40 with round tooth	Class IIa L091102		2025-04-10
T17798 - Acetabular reamer Ø41 with round tooth	Class IIa L091102		2025-04-10
T17799 - Acetabular reamer Ø42 with round tooth	Class IIa L091102		2025-04-10
T17800 - Acetabular reamer Ø43 with round tooth	Class IIa L091102		2025-04-10
T17801 - Acetabular reamer Ø44 with round tooth	Class IIa L091102		2025-04-10
T17802 - Acetabular reamer Ø45 with round tooth	Class IIa L091102		2025-04-10
T17803 - Acetabular reamer Ø46 with round tooth	Class IIa L091102		2025-04-10
T17804 - Acetabular reamer Ø47 with round tooth	Class IIa L091102		2025-04-10
T17805 - Acetabular reamer Ø48 with round tooth	Class IIa L091102		2025-04-10
T17806 - Acetabular reamer Ø49 with round tooth	Class IIa L091102		2025-04-10
T17807 - Acetabular reamer Ø50 with round tooth	Class IIa L091102		2025-04-10
T17808 - Acetabular reamer Ø51 with round tooth	Class IIa L091102		2025-04-10
T17809 - Acetabular reamer Ø52 with round tooth	Class IIa L091102		2025-04-10
T17810 - Acetabular reamer Ø53 with round tooth	Class IIa L091102		2025-04-10
T17811 - Acetabular reamer Ø54 with round tooth	Class IIa L091102		2025-04-10
T17812 - Acetabular reamer Ø55 with round tooth	Class IIa L091102		2025-04-10
T17813 - Acetabular reamer Ø56 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T17814 - Acetabular reamer Ø57 with round tooth	Class IIa L091102		2025-04-10
T17815 - Acetabular reamer Ø58 with round tooth	Class IIa L091102		2025-04-10
T17816 - Acetabular reamer Ø59 with round tooth	Class IIa L091102		2025-04-10
T17817 - Acetabular reamer Ø60 with round tooth	Class IIa L091102		2025-04-10
T17818 - Acetabular reamer Ø61 with round tooth	Class IIa L091102		2025-04-10
T17819 - Acetabular reamer Ø62 with round tooth	Class IIa L091102		2025-04-10
T17820 - Acetabular reamer Ø63 with round tooth	Class IIa L091102		2025-04-10
T17821 - Acetabular reamer Ø64 with round tooth	Class IIa L091102		2025-04-10
T17822 - Acetabular reamer Ø65 with round tooth	Class IIa L091102		2025-04-10
T17823 - Acetabular reamer Ø66 with round tooth	Class IIa L091102		2025-04-10
T17824 - Acetabular reamer Ø67 with round tooth	Class IIa L091102		2025-04-10
T17825 - Acetabular reamer Ø68 with round tooth	Class IIa L091102		2025-04-10
T17826 - Acetabular reamer Ø69 with round tooth	Class IIa L091102		2025-04-10
T17827 - Acetabular reamer Ø70 with round tooth	Class IIa L091102		2025-04-10
T17828 - Acetabular reamer Ø71 with round tooth	Class IIa L091102		2025-04-10
T17829 - Acetabular reamer Ø72 with round tooth	Class IIa L091102		2025-04-10
T17830 - Acetabular reamer Ø73 with round tooth	Class IIa L091102		2025-04-10
T17831 - Acetabular reamer Ø74 with round tooth	Class IIa L091102		2025-04-10
T17832 - Acetabular reamer Ø75 with round tooth	Class IIa L091102		2025-04-10
T17833 - Acetabular reamer Ø76 with round tooth	Class IIa L091102		2025-04-10
T17834 - Acetabular reamer Ø77 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T17835 - Acetabular reamer Ø78 with round tooth	Class IIa L091102		2025-04-10
T17836 - Acetabular reamer Ø79 with round tooth	Class IIa L091102		2025-04-10
T17837 - Acetabular reamer Ø80 with round tooth	Class IIa L091102		2025-04-10
T18010 - Acetabular reamer Ø36 with round tooth	Class IIa L091102		2025-04-10
T18011 - Acetabular reamer Ø37 with round tooth	Class IIa L091102		2025-04-10
T18012 - Acetabular reamer Ø38 with round tooth	Class IIa L091102		2025-04-10
T18013 - Acetabular reamer Ø39 with round tooth	Class IIa L091102		2025-04-10
T18014 - Acetabular reamer Ø40 with round tooth	Class IIa L091102		2025-04-10
T18015 - Acetabular reamer Ø41 with round tooth	Class IIa L091102		2025-04-10
T18016 - Acetabular reamer Ø42 with round tooth	Class IIa L091102		2025-04-10
T18017 - Acetabular reamer Ø43 with round tooth	Class IIa L091102		2025-04-10
T18018 - Acetabular reamer Ø44 with round tooth	Class IIa L091102		2025-04-10
T18019 - Acetabular reamer Ø45 with round tooth	Class IIa L091102		2025-04-10
T18020 - Acetabular reamer Ø46 with round tooth	Class IIa L091102		2025-04-10
T18021 - Acetabular reamer Ø47 with round tooth	Class IIa L091102		2025-04-10
T18022 - Acetabular reamer Ø48 with round tooth	Class IIa L091102		2025-04-10
T18023 - Acetabular reamer Ø49 with round tooth	Class IIa L091102		2025-04-10
T18024 - Acetabular reamer Ø50 with round tooth	Class IIa L091102		2025-04-10
T18025 - Acetabular reamer Ø51 with round tooth	Class IIa L091102		2025-04-10
T18026 - Acetabular reamer Ø52 with round tooth	Class IIa L091102		2025-04-10
T18027 - Acetabular reamer Ø53 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T18028 - Acetabular reamer Ø54 with round tooth	Class IIa L091102		2025-04-10
T18029 - Acetabular reamer Ø55 with round tooth	Class IIa L091102		2025-04-10
T18030 - Acetabular reamer Ø56 with round tooth	Class IIa L091102		2025-04-10
T18031 - Acetabular reamer Ø57 with round tooth	Class IIa L091102		2025-04-10
T18032 - Acetabular reamer Ø58 with round tooth	Class IIa L091102		2025-04-10
T18033 - Acetabular reamer Ø59 with round tooth	Class IIa L091102		2025-04-10
T18034 - Acetabular reamer Ø60 with round tooth	Class IIa L091102		2025-04-10
T18035 - Acetabular reamer Ø61 with round tooth	Class IIa L091102		2025-04-10
T18036 - Acetabular reamer Ø62 with round tooth	Class IIa L091102		2025-04-10
T18037 - Acetabular reamer Ø63 with round tooth	Class IIa L091102		2025-04-10
T18038 - Acetabular reamer Ø64 with round tooth	Class IIa L091102		2025-04-10
T18039 - Acetabular reamer Ø65 with round tooth	Class IIa L091102		2025-04-10
T18040 - Acetabular reamer Ø66 with round tooth	Class IIa L091102		2025-04-10
T18041 - Acetabular reamer Ø67 with round tooth	Class IIa L091102		2025-04-10
T18042 - Acetabular reamer Ø68 with round tooth	Class IIa L091102		2025-04-10
T18043 - Acetabular reamer Ø69 with round tooth	Class IIa L091102		2025-04-10
T18044 - Acetabular reamer Ø70 with round tooth	Class IIa L091102		2025-04-10
T18045 - Acetabular reamer Ø71 with round tooth	Class IIa L091102		2025-04-10
T18046 - Acetabular reamer Ø72 with round tooth	Class IIa L091102		2025-04-10
T18047 - Acetabular reamer Ø73 with round tooth	Class IIa L091102		2025-04-10
T18048 - Acetabular reamer Ø74 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T18049 - Acetabular reamer Ø75 with round tooth	Class IIa L091102		2025-04-10
T18050 - Acetabular reamer Ø76 with round tooth	Class IIa L091102		2025-04-10
T18051 - Acetabular reamer Ø77 with round tooth	Class IIa L091102		2025-04-10
T18052 - Acetabular reamer Ø78 with round tooth	Class IIa L091102		2025-04-10
T18053 - Acetabular reamer Ø79 with round tooth	Class IIa L091102		2025-04-10
T18054 - Acetabular reamer Ø80 with round tooth	Class IIa L091102		2025-04-10
T18209 - Acetabular reamer Ø36 with round tooth	Class IIa L091102		2025-04-10
T18210 - Acetabular reamer Ø37 with round tooth	Class IIa L091102		2025-04-10
T18211 - Acetabular reamer Ø38 with round tooth	Class IIa L091102		2025-04-10
T18212 - Acetabular reamer Ø39 with round tooth	Class IIa L091102		2025-04-10
T18213 - Acetabular reamer Ø40 with round tooth	Class IIa L091102		2025-04-10
T18214 - Acetabular reamer Ø41 with round tooth	Class IIa L091102		2025-04-10
T18215 - Acetabular reamer Ø42 with round tooth	Class IIa L091102		2025-04-10
T18216 - Acetabular reamer Ø43 with round tooth	Class IIa L091102		2025-04-10
T18217 - Acetabular reamer Ø44 with round tooth	Class IIa L091102		2025-04-10
T18218 - Acetabular reamer Ø45 with round tooth	Class IIa L091102		2025-04-10
T18219 - Acetabular reamer Ø46 with round tooth	Class IIa L091102		2025-04-10
T18220 - Acetabular reamer Ø47 with round tooth	Class IIa L091102		2025-04-10
T18221 - Acetabular reamer Ø48 with round tooth	Class IIa L091102		2025-04-10
T18222 - Acetabular reamer Ø49 with round tooth	Class IIa L091102		2025-04-10
T18223 - Acetabular reamer Ø50 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T18224 - Acetabular reamer Ø51 with round tooth	Class IIa L091102		2025-04-10
T18225 - Acetabular reamer Ø52 with round tooth	Class IIa L091102		2025-04-10
T18226 - Acetabular reamer Ø53 with round tooth	Class IIa L091102		2025-04-10
T18227 - Acetabular reamer Ø54 with round tooth	Class IIa L091102		2025-04-10
T18228 - Acetabular reamer Ø55 with round tooth	Class IIa L091102		2025-04-10
T18229 - Acetabular reamer Ø56 with round tooth	Class IIa L091102		2025-04-10
T18230 - Acetabular reamer Ø57 with round tooth	Class IIa L091102		2025-04-10
T18231 - Acetabular reamer Ø58 with round tooth	Class IIa L091102		2025-04-10
T18232 - Acetabular reamer Ø59 with round tooth	Class IIa L091102		2025-04-10
T18233 - Acetabular reamer Ø60 with round tooth	Class IIa L091102		2025-04-10
T18234 - Acetabular reamer Ø61 with round tooth	Class IIa L091102		2025-04-10
T18235 - Acetabular reamer Ø62 with round tooth	Class IIa L091102		2025-04-10
T18236 - Acetabular reamer Ø63 with round tooth	Class IIa L091102		2025-04-10
T18237 - Acetabular reamer Ø64 with round tooth	Class IIa L091102		2025-04-10
T18238 - Acetabular reamer Ø65 with round tooth	Class IIa L091102		2025-04-10
T18239 - Acetabular reamer Ø66 with round tooth	Class IIa L091102		2025-04-10
T18240 - Acetabular reamer Ø67 with round tooth	Class IIa L091102		2025-04-10
T18241 - Acetabular reamer Ø68 with round tooth	Class IIa L091102		2025-04-10
T18242 - Acetabular reamer Ø69 with round tooth	Class IIa L091102		2025-04-10
T18243 - Acetabular reamer Ø70 with round tooth	Class IIa L091102		2025-04-10
T18244 - Acetabular reamer Ø71 with round tooth	Class IIa L091102		2025-04-10

[1]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[1]	Date Added
T18245 - Acetabular reamer Ø72 with round tooth	Class IIa L091102		2025-04-10
T18246 - Acetabular reamer Ø73 with round tooth	Class IIa L091102		2025-04-10
T18247 - Acetabular reamer Ø74 with round tooth	Class IIa L091102		2025-04-10
T18248 - Acetabular reamer Ø75 with round tooth	Class IIa L091102		2025-04-10
T18249 - Acetabular reamer Ø76 with round tooth	Class IIa L091102		2025-04-10
T18250 - Acetabular reamer Ø77 with round tooth	Class IIa L091102		2025-04-10
T18251 - Acetabular reamer Ø78 with round tooth	Class IIa L091102		2025-04-10
T18252 - Acetabular reamer Ø79 with round tooth	Class IIa L091102		2025-04-10
T18253 - Acetabular reamer Ø80 with round tooth	Class IIa L091102		2025-04-10

Lian Zhang

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

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.

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.