

Declaration of conformity

Product family: **Polishers / Arkansas stones**

DiaGloss / TopGloss / Exa Special / Exa Composit / Flexi-Snap / CeraGloss / StarGloss / StarTec / Cerapol plus / Exa Cerapol / Cerapol Super / Alphaflex / Alphaflex supergrün / Goldstar / Amalgam Reducer / Nylon Brush / OrthoFlex / Exa Intrapol / Exa Dental / Prophylaxis Pasteless / Prophylaxis Cups / Prophylaxis Cups with nubs / Prophylaxis Brushlets / Screw-In Brushlets / Snap-On Brushlets / TopBrush / Abrasives / Arkansas / CompGloss

Technical-

Documentation: **TD_1 / Product Group_01**

According to Regulation: **(EU) 2017/745**

Class / Rule: **Ila / 5 – Spiegelstrich 2**

Basis-UDI-DI: **++ E31216412DU**

SRN: **LI-MF-000011937**

EMDN Code.: **Q01010403**

UMDNS-Nr.: **16-412 Polishers (Rubber / Arkansas stone)**


Purpose-Determination:

For use in dental practice for users with appropriate qualifications (dental studies). Polishers are universally applicable dental instruments depending on the composition of their functional part (polishing body) and intended use. They are suitable for a wide variety of preparations and the processing of a wide variety of dental and dental technology materials.

We, Edenta Etablissement as manufacturer, hereby declare under our sole responsibility that the medical devices described above and the associated technical documentation comply with Regulation (EU) 2017/745 and all relevant national legislation.

The conformity assessment procedure applied corresponds to: Annex IX, taking into account the applicable harmonized standards and the (GS) Common Specifications), and verified with certificate ID-no. **1000183128**.

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main.

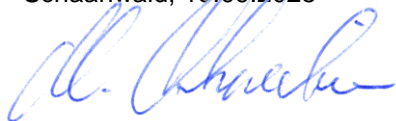
Identification-No.:  0297

Validity of the declaration of conformity: For all batches produced from the date of issue until March 27, 2030 (expiry date of the issued certificates).

The products are not sold sterile.

**Edenta Etablissement,
Industriestrasse 13
LI-9486 Schaanwald**

Schaanwald, 18.09.2025



Meinrad Schreiber
Produkt Management

AS01.025FG-100	0055FG-100	0738RA-100	19032RA-100	SGTK
AS01.025FG-12	0055FG-12	0738RA-12	19032RA-6	ST2530RA-6
AS02.025FG-100	0130RA-100	0739RA-100	19033RA-100	ST2540RA-6
AS02.025FG-12	0130RA-12	0739RA-12	19033RA-6	ST2630RA-6
AS03.025FG-100	0131RA-100	0830RA-100	19034RA-100	ST2640RA-6
AS03.025FG-12	0131RA-12	0830RA-12	19034RA-6	ST2730RA-6
AS04.025FG-100	0132RA-100	0831RA-100	19035RA-100	ST2740RA-6
AS04.025FG-12	0132RA-12	0831RA-12	19035RA-6	ST2830RA-6
AS05.030FG-100	0133RA-100	0832RA-100	19038RA-100	ST2840RA-6
AS05.030FG-12	0133RA-12	0832RA-12	19038RA-6	STTK
AS06.030FG-100	0134RA-100	0834RA-100	19039RA-100	TGTK
AS06.030FG-12	0134RA-12	0834RA-12	19039RA-6	0790SO
AS07SO	0135RA-100	0835RA-100	1932RA-100	0990SO
AS11.025RA-100	0135RA-12	0835RA-12	1932RA-6	0991SO
AS11.025RA-12	0136RA-100	0836RA-100	1933RA-100	19040SO
AS12.025RA-100	0136RA-12	0836RA-12	1933RA-6	19050SO
AS12.025RA-12	0138RA-100	0932RA-100	1934RA-100	1940SO
AS13.025RA-100	0138RA-12	0932RA-12	1934RA-6	1945SO
AS13.025RA-12	0139RA-100	0933RA-100	1935RA-100	30040SO
AS14.025RA-100	0139RA-12	0933RA-12	1935RA-6	30045SO
AS14.025RA-12	0153FG-100	0935RA-100	1938RA-100	30050SO
AS15.030RA-100	0153FG-12	0935RA-12	1938RA-6	30055SO
AS15.030RA-12	0155FG-100	0939RA-100	1939RA-100	1240RA-100
AS16.030RA-100	0155FG-12	0939RA-12	1939RA-6	1241RA-100
AS16.030RA-12	0352RA-100	1232RA-100	20032RA-100	1242RA-100
AS17SO	0352RA-12	1232RA-12	20032RA-6	1243SC-100
AS18SO	0355RA-100	1233RA-100	20033RA-100	1244SC-100
1260UM-50	0355RA-12	1233RA-12	20033RA-6	1245SC-100
1261UM-50	0362RA-100	1235RA-100	20035RA-100	1246RA-100
1270UM-50	0362RA-12	1235RA-12	20035RA-6	1247RA-100
1271UM-50	0365RA-100	1238RA-100	20038RA-100	1248RA-100
1280UM-50	0365RA-12	1238RA-12	20038RA-6	1249RA-100
1281UM-50	0372RA-100	1239RA-100	20039RA-6	1250RA-100
1290UM-50	0372RA-12	1239RA-12	30032RA-6	1251UM-100
1291UM-50	0390SO	18032RA-100	30033RA-6	1252UM-100
1295SO	0432RA-100	18032RA-12	30035RA-6	1253UM-100
FSTK	0432RA-12	18132RA-100	30036RA-6	1254RA-100
GF601.030FG-100	0433RA-100	18132RA-12	30039RA-6	1255RA-100
GF601.030FG-12	0433RA-12	18232RA-100	30053FG-100	1256RA-100
GF601.030RA-100	0435RA-100	18232RA-12	30053FG-6	1257RA-100
GF601.030RA-12	0435RA-12	BRY0133RA-100	30055FG-100	1259RA-100
GF602.040RA-100	0530RA-100	BRY0133RA-12	30055FG-6	1470RA-100
GF602.040RA-12	0530RA-12	BRY0135RA-100	3032RA-6	1471RA-100
GF661.025FG-100	0531RA-100	BRY0135RA-12	3033RA-6	1472RA-100
GF661.025FG-12	0531RA-12	BRY0153FG-100	3035RA-6	1473RA-100
GF661.025RA-100	0532RA-100	BRY0153FG-12	3036RA-6	1475RA-100
GF661.025RA-12	0532RA-12	PRTK	3039RA-6	1476RA-100
GM663.050RA-100	0533RA-100	0332RA-100	3053FG-100	1477RA-100
GM663.050RA-12	0533RA-12	0332RA-6	3055FG-100	1478RA-100
0030RA-100	0534RA-100	0333RA-100	332RA-6	1480SC-100
0030RA-12	0534RA-12	0333RA-6	333RA-6	1481SC-100
0031RA-100	0535RA-100	0334RA-100	335RA-6	1482SC-100
0031RA-12	0535RA-12	0334RA-6	336RA-6	1483SC-100
0032RA-100	0536RA-100	0335RA-100	353FG-100	1485SC-100
0032RA-12	0536RA-12	0335RA-6	355FG-100	1486SC-100
0033RA-100	0730RA-100	0336RA-100	CGTK	1490UM-100
0033RA-12	0730RA-12	0336RA-6	CPTK	1491UM-100
0034RA-100	0731RA-100	0339RA-100	R25010SO	1500RA-5
0034RA-12	0731RA-12	0339RA-6	R2520RA-6	1501RA-5
0035RA-100	0732RA-100	1032RA-6	R2530RA-6	1502RA-5
0035RA-12	0732RA-12	1033RA-6	R2540RA-6	
0036RA-100	0733RA-100	1035RA-6	R2620RA-6	
0036RA-12	0733RA-12	1039RA-6	R2630RA-6	
0038RA-100	0734RA-100	1132RA-6	R2640RA-6	
0038RA-12	0734RA-12	1133RA-6	R2720RA-6	
0039RA-100	0735RA-100	1135RA-6	R2730RA-6	
0039RA-12	0735RA-12	1139RA-6	R2740RA-6	
0053FG-100	0736RA-100	1332RA-6	R2830RA-6	
0053FG-12	0736RA-12	1333RA-6	R2840RA-6	

Declaration of conformity

Product family: **Diamond Instruments**

Diamond-FG / Diamond-RA / Bambino / Reducer / Rapid Grinder / Turbo Diamonds / Perioed / Magic Set / Crown Prep-Set / K-Diamonds / ZirTec / Diacut / White Tiger / Depth Marker TM / Diamond Shaper / KS Diamonds / Diamonds Strips / StripFIX

Technical-

Documentation: **TD_1 / Product Group_02**

According
to Regulation: **(EU) 2017/745**

Class / Rule: **Ila / 6**

Basis-UDI-DI: **++E31216670EL / ++E31263358FH**

SRN: **LI-MF-000011937**

EMDN Code.: **Z12110102 / Q01010403**

UMDNS-Nr.: **16-670 (Burs, dental diamond)**


Purpose-Determination:

For use in dental practice for users with appropriate qualifications (dental studies). Removal of carious tooth substance and preparation of retention, resistance and outline forms, finishing of crown stumps, cavity edges, smoothing of fillings, cavity preparation, excavation of the cavity, drilling out of old fillings, cutting open crowns and bridges, dental measure for preparing a tooth to receive a Crown. Used for removing cement after cementation of crowns, bridges, inlays, onlays or veneers. Used for finishing and polishing interproximal fillings and for removing excess filling material. For dental hygienists to enable removal of discoloration that cannot be accessed with their instruments. In interproximal reduction (IPR), used for reducing interproximal enamel during orthodontic procedures.

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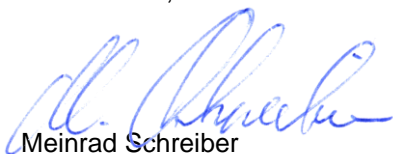
Identification-No.:  0297

Validity of the declaration of conformity: For all batches produced from the date of issue until March 27, 2030 (expiry date of the issued certificates).

The products are not sold sterile.

**Edenta Etablissement,
Industriestrasse 13
LI-9486 Schaanwald**

Schaanwald, 18.09.2025



Meinrad Schreiber
Produkt Management

A848.314.018	C859L.314.016	FW878K.314.014	F836.314.012	F860.314.014
BA001.313.007	C859.314.010	FW878K.314.016	F837KR.314.010	F861.314.012
BA010.313.008	C859.314.012	FW878K.314.018	F837KR.314.012	F862.314.009
BA010.313.010	C859.314.014	FW878K.314.020	F837KR.314.014	F862.314.010
BA108.313.008	C859.314.016	FW878K.314.022	F837KR.314.016	F862.314.012
BA137.313.007	C859.314.018	FW878.314.010	F837L.314.012	F862.314.014
BA138.313.007	C860.314.010	FW878.314.012	F837.314.012	F862.314.016
BA160.313.007	C860.314.012	FW878.314.014	F837.314.014	F863.314.010
BA171.313.012	C861.314.012	FW879K.314.012	F839.314.010	F863.314.012
BA274.313.007	C862.314.009	FW879K.314.014	F839.314.014	F863.314.014
BA277.313.009	C862.314.010	FW879K.314.016	F845KR.314.016	F863.314.016
BA294.313.007	C862.314.012	FW879K.314.018	F845KR.314.018	F863.314.018
BA295.313.007	C862.314.014	FW879.314.014	F845KR.314.025	F864.314.012
C368.314.010	C862.314.016	FW880.314.012	F846KR.314.016	F864.314.014
C368.314.016	C863.204.012	FW881.314.014	F847KR.314.016	F864.314.016
C368.314.018	C863.314.010	FW881.314.016	F847KR.314.023	F877.314.010
C368.314.023	C863.314.012	FW899.314.027	F847.314.010	F877.314.012
C369.314.025	C863.314.014	F368.314.010	F847.314.012	F878K.314.014
C379.314.012	C863.314.016	F368.314.016	F847.314.014	F878K.314.016
C379.314.014	C864.314.016	F368.314.018	F847.314.016	F878K.314.018
C379.314.016	C878.314.010	F368.314.023	F848.314.010	F878K.314.021
C379.314.018	C878.314.014	F369.314.025	F848.314.012	F878.314.008
C379.314.023	C879.314.012	F370.314.023	F848.314.014	F878.314.010
C379.314.029	C879.314.014	F379.314.012	F848.314.016	F878.314.012
C390.314.016	C879.314.016	F379.314.014	F848.314.018	F878.314.014
C392.314.016	C881.314.012	F379.314.016	F849.314.012	F878.314.016
C801.314.012	C881.314.014	F379.314.018	F850L.314.012	F879K.314.012
C801.314.014	C882.314.012	F379.314.023	F850L.314.014	F879K.314.014
C801.314.016	C889.314.009	F379.314.029	F850.314.010	F879K.314.016
C801.314.018	C889.314.010	F390.314.016	F850.314.012	F879K.314.018
C801.314.021	C972.315.020	F392.314.016	F850.314.014	F879L.314.012
C801.314.023	C986.314.026	F801.314.007	F850.314.016	F879L.314.014
C801.314.025	C986.314.031	F801.314.008	F850.314.018	F879.314.010
C801.314.029	C986.314.041	F801.314.009	F850.314.023	F879.314.012
C801.314.035	FV368.314.020	F801.314.010	F851.314.010	F879.314.014
C830L.314.014	FV801.314.014	F801.314.012	F851.314.012	F879.314.016
C830.314.012	FV801.314.021	F801.314.014	F852.314.010	F879.314.018
C831L.206.012	FV830L.314.012	F801.314.016	F852.314.012	F880.314.012
C831.205.012	FV850.314.012	F801.314.018	F856L.314.014	F880.314.014
C832L.206.014	FV863.314.012	F801.314.021	F856L.314.016	F881.314.010
C832.205.014	FV863.314.016	F801.314.023	F856L.314.018	F881.314.012
C833.314.021	FV877K.314.016	F801.314.025	F856L.314.020	F881.314.014
C833.314.031	FV878K.314.022	F801.314.029	F856.314.009	F881.314.016
C847.314.010	FV878.314.012	F801.314.035	F856.314.010	F881.314.018
C848.314.010	FV878.314.014	F802.314.016	F856.314.012	F882.314.012
C848.314.012	FV879K.314.012	F805.314.014	F856.314.014	F882.314.014
C848.314.014	FV879K.314.016	F822.314.012	F856.314.016	F885.314.010
C848.314.016	FV879.314.014	F830L.314.012	F856.314.018	F885.314.012
C850L.314.014	FV881.314.014	F830L.314.014	F856.314.021	F885.314.014
C850.314.010	FW368.314.020	F830L.314.016	F856.314.025	F886.314.012
C850.314.012	FW379.314.023	F830.314.010	F857.314.014	F886.314.014
C850.314.014	FW801.314.014	F830.314.012	F858.314.010	F886.314.016
C850.314.016	FW801.314.021	F830.314.014	F858.314.012	F888.314.012
C850.314.018	FW830L.314.012	F831L.206.012	F858.314.014	F889.314.009
C852.314.010	FW830L.314.014	F831.205.012	F858.314.016	F889.314.010
C852.314.012	FW830L.314.016	F832L.206.014	F859L.314.010	F898.314.016
C856.314.010	FW835KR.314.012	F832.205.014	F859L.314.014	F899.314.021
C856.314.012	FW837KR.314.014	F833.314.018	F859L.314.016	F899.314.027
C856.314.016	FW847KR.314.016	F833.314.021	F859.314.010	F970.313.023
C858.314.010	FW850.314.012	F833.314.031	F859.314.012	F972.315.020
C858.314.012	FW860.314.012	F835KR.314.012	F859.314.014	F980.313.027
C858.314.014	FW863.314.012	F835.314.010	F859.314.016	F985.313.031
C858.314.016	FW863.314.016	F836KR.314.010	F859.314.018	F986.314.026
C859L.314.010	FW877K.314.012	F836KR.314.012	F860.314.010	F986.314.031
C859L.314.014	FW877K.314.016	F836.314.010	F860.314.012	F986.314.041

F998.314.016	GW847KR.314.016	G801.316.016	G836KR.314.016	G850.314.016
F998.314.021	GW847KR.314.018	G801.316.018	G836.314.010	G850.314.018
F998.314.023	GW847.314.014	G801.316.023	G836.314.012	G850.314.023
GF844.314.014	GW847.314.016	G802.314.012	G836.314.014	G850.314.031
GF844.314.016	GW848.314.018	G802.314.014	G836.314.016	G851.314.012
GV368.314.020	GW850.314.012	G802.314.016	G836.314.018	G851.314.016
GV368.314.023	GW850.314.014	G802.314.018	G837KR.314.010	G852.314.012
GV379.314.023	GW850.314.016	G802.314.023	G837KR.314.012	G852.314.023
GV801.314.014	GW855.314.025	G805.314.012	G837KR.314.014	G855.314.012
GV801.314.021	GW856L.314.018	G805.314.014	G837KR.314.016	G855.314.014
GV801.314.023	GW856.314.014	G805.314.016	G837L.314.010	G855.314.025
GV811.314.033	GW856.314.016	G805.314.018	G837L.314.012	G856L.314.014
GV830L.314.012	GW856.314.018	G805.314.021	G837L.314.014	G856L.314.016
GV830L.314.014	GW856.314.021	G806.314.010	G837L.314.016	G856L.314.018
GV830L.314.016	GW858.314.014	G806.314.012	G837L.314.018	G856L.314.020
GV835KR.314.012	GW862.314.014	G806.314.014	G837.314.010	G856.314.012
GV837KR.314.014	GW863.314.012	G806.314.016	G837.314.012	G856.314.014
GV847KR.314.016	GW863.314.016	G806.314.018	G837.314.014	G856.314.016
GV847KR.314.018	GW877K.314.012	G807.314.012	G837.314.016	G856.314.018
GV847.314.014	GW877K.314.016	G807.314.014	G837.314.018	G856.314.021
GV847.314.016	GW878K.314.014	G807.314.016	G838.314.010	G856.314.025
GV848.314.018	GW878K.314.016	G807.314.018	G838.314.012	G857.314.012
GV850.314.012	GW878K.314.018	G807.314.021	G838.314.014	G857.314.014
GV850.314.014	GW878K.314.020	G811.314.033	G842.314.012	G857.314.016
GV850.314.016	GW878K.314.022	G811.314.037	G842.314.014	G858.314.010
GV855.314.025	GW878.314.012	G811.314.047	G842.314.018	G858.314.012
GV856L.314.018	GW878.314.014	G813L.314.014	G845KR.314.016	G858.314.014
GV856.314.014	GW879K.314.012	G813L.314.016	G845KR.314.018	G858.314.016
GV856.314.016	GW879K.314.014	G813.314.014	G845KR.314.025	G858.314.018
GV856.314.018	GW879K.314.016	G813.314.016	G845.314.012	G859L.314.014
GV856.314.021	GW879K.314.018	G815.314.018	G845.314.014	G859L.314.016
GV858.314.014	GW879.314.014	G815.314.023	G846KR.314.016	G859L.314.018
GV862.314.014	GW880.314.012	G815.314.027	G846S.314.025	G859.314.010
GV863.314.012	GW881.314.014	G817.314.047	G846.314.012	G859.314.012
GV863.314.016	GW881.314.016	G818.314.040	G846.314.016	G859.314.014
GV877K.314.012	GW899.314.027	G818.314.050	G846.314.025	G859.314.016
GV877K.314.016	GW909.314.040	G822.314.008	G847KR.314.016	G859.314.018
GV878K.314.014	G368.314.016	G822.314.009	G847KR.314.023	G859.314.021
GV878K.314.016	G368.314.018	G822.314.010	G847.314.010	G860.314.010
GV878K.314.018	G368.314.023	G822.314.012	G847.314.012	G860.314.012
GV878K.314.020	G369.314.025	G830L.314.012	G847.314.014	G860.314.014
GV878K.314.022	G370.314.023	G830L.314.014	G847.314.016	G860.314.016
GV878.314.012	G379.314.012	G830L.314.016	G847.314.018	G861.314.012
GV878.314.014	G379.314.014	G830L.314.018	G847.314.023	G861.314.014
GV879K.314.012	G379.314.016	G830L.314.021	G848L.314.014	G862.314.010
GV879K.314.014	G379.314.018	G830L.314.025	G848L.314.016	G862.314.012
GV879K.314.016	G379.314.023	G830.314.010	G848L.314.018	G862.314.014
GV879K.314.018	G379.314.029	G830.314.012	G848.314.010	G862.314.016
GV879.314.014	G653.314.018	G830.314.014	G848.314.012	G862.314.018
GV880.314.012	G656.314.018	G830.314.016	G848.314.014	G863L.314.016
GV881.314.014	G801L.314.014	G830.314.018	G848.314.016	G863.314.012
GV881.314.016	G801L.314.016	G830.314.021	G848.314.018	G863.314.014
GV909.314.040	G801L.314.023	G835KR.314.010	G848.314.023	G863.314.016
GW368.314.020	G801L.314.029	G835KR.314.012	G849.314.012	G863.314.018
GW368.314.023	G801.314.012	G835KR.314.014	G849.314.016	G863.314.021
GW379.314.023	G801.314.014	G835KR.314.016	G849.314.025	G864.314.014
GW801.314.014	G801.314.016	G835.314.009	G850KR.314.014	G864.314.016
GW801.314.021	G801.314.018	G835.314.010	G850KR.314.018	G864.314.018
GW801.314.023	G801.314.021	G835.314.012	G850L.314.012	G877.314.012
GW811.314.033	G801.314.023	G835.314.014	G850L.314.014	G878K.314.012
GW830L.314.012	G801.314.025	G835.314.016	G850L.314.016	G878K.314.014
GW830L.314.014	G801.314.029	G835.314.018	G850L.314.018	G878K.314.016
GW830L.314.016	G801.314.035	G836KR.314.010	G850.314.010	G878K.314.018
GW835KR.314.012	G801.314.042	G836KR.314.012	G850.314.012	G878K.314.021
GW837KR.314.014	G801.316.014	G836KR.314.014	G850.314.014	G878.314.010

G878.314.012	K881.314.016	SG835KR.314.014	SG863.314.016	T837.314.016SC
G878.314.014	K850.314.014	SG835.314.010	SG863.314.018	T842.314.018C
G878.314.016	K850.314.016	SG835.314.012	SG863.314.021	T846.314.016SC
G878.314.018	K881.314.012	SG835.314.014	SG864.314.016	T848L.314.014C
G879K.314.012	KF881.314.012	SG835.314.016	SG864.314.018	T848.314.016C
G879K.314.014	K882.314.012	SG836KR.314.014	SG878K.314.012	T848.314.016SC
G879K.314.016	K899.314.031	SG836.314.012	SG878K.314.014	T850.314.012C
G879K.314.018	KS0.314.010	SG836.314.014	SG878K.314.016	T850.314.014C
G879K.314.021	KS0F.314.010	SG836.314.016	SG878K.314.018	T850.314.014SC
G879K.314.023	KS1.314.012	SG836.314.027	SG878K.314.021	T850.314.016C
G879L.314.012	KS1L.314.012	SG837KR.314.012	SG878.314.012	T850.314.016SC
G879L.314.014	KS2.314.014	SG837KR.314.014	SG878.314.014	T850.314.018C
G879.314.010	KS3.314.016	SG837KR.314.016	SG878.314.016	T850.314.018SC
G879.314.012	KT856.314.016	SG837L.314.014	SG879K.314.012	T856.314.012C
G879.314.014	KT881.314.016	SG837L.314.016	SG879K.314.014	T856.314.012SC
G879.314.016	SGW837KR.314.016	SG837.314.012	SG879K.314.016	T859.314.018SC
G879.314.018	SG368.314.016	SG837.314.014	SG879K.314.018	T863.314.014C
G880.314.012	SG368.314.018	SG837.314.016	SG879K.314.021	T878K.314.014C
G880.314.014	SG368.314.023	SG837.314.018	SG879L.314.012	T878K.314.014SC
G881.314.010	SG379.314.016	SG838.314.012	SG879L.314.014	T878K.314.016SC
G881.314.012	SG379.314.018	SG842.314.012	SG879.314.012	T878K.314.018C
G881.314.014	SG379.314.023	SG842.314.014	SG879.314.014	T878.314.012C
G881.314.016	SG379.314.029	SG847.314.014	SG879.314.016	T878.314.012SC
G881.314.018	SG652.314.018	SG847.314.016	SG879.314.018	T878.314.014C
G882.314.012	SG655.314.018	SG847.314.018	SG880.314.014	T878.314.014SC
G882.314.014	SG656.314.018	SG848L.314.014	SG881KS.314.012	T879K.314.012SC
G883.314.010	SG801L.314.014	SG848L.314.016	SG881KS.314.014	T879K.314.014C
G884.314.012	SG801L.314.016	SG848L.314.018	SG881KS.314.015	T879K.314.014SC
G885.314.012	SG801L.314.023	SG848.314.016	SG881KS.314.016	T879K.314.016C
G885.314.014	SG801L.314.029	SG848.314.018	SG881.314.014	T879K.314.016SC
G885.314.016	SG801.314.012	SG848.314.023	SG881.314.016	T879L.314.012SC
G886.314.012	SG801.314.014	SG850KR.314.014	SG881.314.018	T879L.314.014SC
G886.314.014	SG801.314.016	SG850KR.314.018	SG882.314.014	T879.314.012C
G886.314.016	SG801.314.018	SG850L.314.014	SG885.314.012	T879.314.012SC
G888.314.012	SG801.314.021	SG850L.314.016	SG885.314.014	T879.314.014C
G889.314.009	SG801.314.023	SG850L.314.018	SG885.314.018	T879.314.016C
G889.314.010	SG801.314.025	SG850.314.014	SG886.314.012	T881.314.012C
G898.314.016	SG801.314.029	SG850.314.016	SG886.314.014	T881.314.014C
G899.314.021	SG801.314.035	SG850.314.018	SG886.314.016	T882.314.012C
G899.314.027	SG801.316.016	SG850.314.023	SG889.314.010	T882.314.014C
G899.314.031	SG801.316.018	SG852.314.037	SG899.314.021	T886.314.012SC
G909.314.037	SG802.314.014	SG855.314.014	SG899.314.027	T886.314.014SC
G909.314.040	SG802.314.016	SG855.314.025	SG899.314.031	TM05.314.009
KC369.314.025	SG802.314.018	SG856L.314.014	SG909.314.040	TM10.314.009
KC801L.314.014	SG805.314.014	SG856L.314.016	SG998.314.016	TM15.314.009
KC856.314.016	SG805.314.016	SG856L.314.018	SG998.314.021	TM20.314.009
KC859L.314.010	SG805.314.018	SG856L.314.020	SG998.314.023	UF368.314.023
KC879.314.014	SG805.314.021	SG856.314.012	S801.313.014	UF859.314.010
KC881.314.016	SG806.314.014	SG856.314.016	S805.313.012	UF859.314.016
KF369.314.025	SG806.314.016	SG856.314.018	S835.313.008	UF862.314.010
KF379L.315.012	SG806.314.018	SG856.314.021	S835.313.012	UF863.314.012
KF801L.314.014	SG807.314.016	SG856.314.025	S845.313.012	VT830L.314.012
KF856.314.016	SG811.314.033	SG857.314.014	T811.314.033C	VT830L.314.014
KF859L.314.010	SG811.314.037	SG858.314.014	T822.314.012SC	VT850.314.016
KF879.314.014	SG811.314.047	SG858.314.016	T830L.314.012C	VT879.314.014
KF881.314.016	SG813.314.018	SG858.314.018	T830L.314.012SC	V368.314.020
KUF369.314.025	SG822.314.012	SG859L.314.016	T830L.314.014C	V801.314.014
KUF801L.314.014	SG830L.314.014	SG859L.314.018	T830L.314.014SC	V801.314.021
KUF856.314.016	SG830L.314.016	SG859.314.018	T830L.314.016C	V830L.314.012
KUF859L.314.010	SG830L.314.018	SG860.314.014	T830L.314.016SC	V830L.314.014
KUF879.314.014	SG830L.314.021	SG862.314.012	T830L.314.018SC	V830L.314.016
KUF881.314.016	SG830L.314.025	SG862.314.014	T836.314.012SC	V835KR.314.012
K802L.314.021	SG830.314.012	SG862.314.016	T837.314.012C	V837KR.314.014
K856.314.016	SG830.314.014	SG862.314.018	T837.314.012SC	V845KR.314.016
K879.314.014	SG830.314.016	SG863.314.012	T837.314.014C	V846KR.314.016

V850.314.012	655.314.018	807.314.014	835.314.007	847.314.012
V850.314.014	801L.314.014	807.314.016	835.314.008	847.314.014
V863.314.012	801L.314.016	807.314.018	835.314.009	847.314.016
V863.314.016	801L.314.023	807.314.021	835.314.010	847.314.018
V878K.314.014	801L.314.029	807.314.023	835.314.012	847.314.023
V878.314.010	801.204.010	808.314.018	835.314.014	848L.314.012
V878.314.012	801.204.012	808.314.023	835.314.016	848L.314.014
V878.314.014	801.204.014	811.314.033	835.314.018	848L.314.016
V879K.314.012	801.204.016	811.314.037	836KR.314.008	848L.314.018
V879K.314.014	801.204.018	811.314.047	836KR.314.010	848L.314.021
V879K.314.016	801.204.023	813L.314.014	836KR.314.012	848.204.016
V879.314.014	801.204.029	813L.314.016	836KR.314.014	848.314.010
V880.314.012	801.314.007	813.314.010	836KR.314.016	848.314.012
V881.314.014	801.314.008	813.314.014	836.314.008	848.314.014
W368.314.020	801.314.009	813.314.016	836.314.010	848.314.016
W379.314.023	801.314.010	813.314.018	836.314.012	848.314.018
W801.314.014	801.314.012	815.314.012	836.314.014	848.314.023
W801.314.021	801.314.014	815.314.016	836.314.016	849.204.016
W801.314.023	801.314.016	815.314.018	836.314.018	849.314.009
W830L.314.012	801.314.018	815.314.027	837KR.314.010	849.314.010
W830L.314.014	801.314.021	817.314.047	837KR.314.012	849.314.012
W830L.314.016	801.314.023	818.314.035	837KR.314.014	849.314.016
W835KR.314.012	801.314.025	818.314.040	837KR.314.016	850KR.314.014
W837KR.314.014	801.314.029	818.314.050	837KR.314.018	850KR.314.018
W845KR.314.016	801.314.035	820.314.040	837L.314.010	850L.314.012
W846KR.314.016	801.314.042	822.314.008	837L.314.012	850L.314.014
W846KR.314.023	801.316.010	822.314.009	837L.314.014	850L.314.016
W847KR.314.016	801.316.012	822.314.010	837L.314.016	850L.314.018
W847.314.016	801.316.014	822.314.012	837L.314.018	850.204.012
W850.314.012	801.316.016	825.314.018	837.314.010	850.314.010
W850.314.014	801.316.018	825.314.025	837.314.012	850.314.012
W863.314.012	801.316.023	825.314.040	837.314.014	850.314.014
W863.314.016	802L.314.013	825.314.050	837.314.016	850.314.016
W877K.314.012	802L.314.016	830L.314.012	837.314.018	850.314.018
W877K.314.016	802L.314.021	830L.314.014	838.314.008	850.314.023
W878K.314.014	802.314.008	830L.314.016	838.314.009	850.314.031
W878K.314.016	802.314.009	830L.314.018	838.314.010	851.314.010
W878K.314.018	802.314.010	830L.314.021	838.314.012	851.314.012
W878K.314.020	802.314.012	830L.314.025	838.314.014	851.314.016
W878K.314.022	802.314.014	830.314.008	839.314.010	852.314.010
W878.314.010	802.314.016	830.314.009	839.314.012	852.314.012
W878.314.012	802.314.018	830.314.010	839.314.014	852.314.023
W878.314.014	802.314.023	830.314.012	839.314.016	855.314.012
W879K.314.012	805.204.010	830.314.014	840.314.010	855.314.014
W879K.314.014	805.204.012	830.314.016	840.314.012	855.314.025
W879K.314.016	805.204.014	830.314.018	840.314.014	856L.314.014
W879K.314.018	805.204.016	830.314.021	840.314.016	856L.314.016
W879.314.014	805.314.008	831L.206.012	842.314.012	856L.314.018
W880.314.012	805.314.009	831.205.012	842.314.014	856L.314.020
W881.314.014	805.314.010	832L.206.014	845KR.314.018	856.314.009
W899.314.027	805.314.012	832.205.014	845KR.314.025	856.314.010
368.204.016	805.314.014	833.314.018	845.204.010	856.314.012
368.314.010	805.314.016	833.314.021	845.204.014	856.314.014
368.314.016	805.314.018	833.314.031	845.314.009	856.314.016
368.314.018	805.314.021	834A.314.031	845.314.010	856.314.018
368.314.023	805.314.023	834.314.016	845.314.012	856.314.021
369.314.025	806.314.009	834.314.021	845.314.014	856.314.025
379.314.012	806.314.010	835KR.314.008	845.314.016	857.314.012
379.314.014	806.314.012	835KR.314.010	846KR.314.016	857.314.014
379.314.016	806.314.014	835KR.314.012	846.314.012	857.314.016
379.314.018	806.314.016	835KR.314.014	846.314.016	858.314.010
379.314.023	806.314.018	835.204.010	847KR.314.016	858.314.012
379.314.029	807L.314.018	835.204.012	847KR.314.023	858.314.014
390.314.016	807.314.010	835.204.014	847.204.025	858.314.016
392.314.016	807.314.012	835.204.016	847.314.010	858.314.018

859L.314.010	878.314.018	PCXDS2
859L.314.014	879K.314.012	PXDS3
859L.314.016	879K.314.014	PFXDS3
859L.314.018	879K.314.016	PCXDS3
859.204.012	879K.314.018	DS6
859.204.016	879K.314.021	FDS6
859.314.010	879L.314.012	CDS6
859.314.012	879L.314.014	SF-M
859.314.014	879.314.010	SF-F
859.314.016	879.314.012	SF-SF
859.314.018	879.314.014	SF-SS
859.314.021	879.314.016	SF-H
860.204.012	879.314.018	SF-SET1
860.314.010	880.314.010	KDSC1
860.314.012	880.314.012	KDSF2
860.314.014	880.314.014	KDSM3
860.314.016	880.314.016	KDSF3
861SE.314.012	881.314.010	KDSM4
861.314.012	881.314.012	
861.314.014	881.314.014	
862.204.012	881.314.016	
862.314.009	881.314.018	
862.314.010	882.314.012	
862.314.012	882.314.014	
862.314.014	883.314.010	
862.314.016	884.314.010	
862.314.018	885.314.008	
862.314.021	885.314.010	
863L.314.016	885.314.012	
863SE.314.012	885.314.014	
863.204.012	885.314.016	
863.204.016	886.314.010	
863.204.018	886.314.012	
863.314.010	886.314.014	
863.314.012	886.314.016	
863.314.014	888.314.012	
863.314.016	889.314.009	
863.314.018	889.314.010	
864.314.012	898.314.016	
864.314.014	899.314.021	
864.314.016	899.314.027	
864.314.018	899.314.031	
868A.314.018	909.314.027	
868A.314.021	909.314.037	
874K.314.010	909.314.040	
874.314.009	970.313.023	
875.314.009	980.313.027	
875.314.010	986.314.041	
876K.314.012	998.314.026	
876.314.009	DS2	
877K.314.012	FDS2	
877.314.009	CDS2	
877.314.010	DS3	
877.314.012	FDS3	
878K.314.012	CDS3	
878K.314.014	PDS2	
878K.314.016	PFDS2	
878K.314.018	PCDS2	
878K.314.021	PDS3	
878.314.008	PFDS3	
878.314.009	PCDS3	
878.314.010	FXDS3	
878.314.012	CXDS3	
878.314.014	PXDS2	
878.314.016	PFXDS2	

Declaration of conformity

Product family: **Tungsten carbide- and steel burs / Finishers**
Carbide Burs / Crown separator / PowerCut / Finishers / Periodontic / Amalgam remover
/ Steel Burs / RA-Mandrels

Technical-
Documentation: **TD_1 / Produkt-Gruppe_03**

According
to Regulation: **(EU) 2017/745**

Class / Rule: **Ila / 6**

Basis-UDI-DI: **++ E31210521CQ / ++E31235170EA**

SRN: **LI-MF-000011937**

EMDN Code.: **L159007**

UMDNS-Nr.: **10-521 (Burs, dental)**

Purpose-Determination:

For use in dental practice for users with appropriate qualifications (dental studies). Removal of carious tooth substance and preparation of retention, resistance and outline forms, finishing of crown stumps, cavity edges, smoothing of fillings, cavity preparation, excavation of the cavity, drilling out of old fillings, cutting open crowns and bridges, dental measure for preparing a tooth to receive a Crown.

We, Edenta Etablissement as manufacturer, hereby declare under our sole responsibility that the medical devices described above and the associated technical documentation comply with Regulation (EU) 2017/745 and all relevant national legislation.

The conformity assessment procedure applied corresponds to: Annex IX, taking into account the applicable harmonized standards and the (GS) Common Specifications, and verified with certificate ID-no. **1000183128**.

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main.

Identification-No.: **CE** 0297

Validity of the declaration of conformity: For all batches produced from the date of issue until March 27, 2030 (expiry date of the issued certificates).

The products are not sold sterile.

**Edenta Etablissement,
Industriestrasse 13
LI-9486 Schaanwald**

Schaanwald, 18.09.2025



Meinrad Schreiber
Produkt Management

1.204.005	36.204.012	C1SX.204.016	H1.314.008	T379X.204.018
1.204.006	36.204.014	C1SX.204.018	H1.314.010	T379X.204.023
1.204.007	36.204.016	C1SX.204.021	H1.314.012	T7X.314.012
1.204.008	36.204.018	C1SX.204.023	H1.314.014	T7XL.314.012
1.204.009	36.204.021	C1SX.205.012	H1.314.016	T7XL.314.014
1.204.010	36.204.023	C1SX.205.014	H1.314.018	TC132.204.008
1.204.012	38.204.007	C1SX.205.016	H1.314.021	TC132.314.008
1.204.014	38.204.008	C1SX.205.018	H1.314.023	TC132F.314.008
1.204.016	38.204.009	C1SX.205.021	H152.314.009	TC132UF.314.008
1.204.018	38.204.010	C1SX.205.023	H152.315.009	TC133.314.010
1.204.021	38.204.012	C1SXN.204.010	H1SEB.205.004	TC133F.314.010
1.204.023	38.204.014	C1SXN.204.012	H1SEB.205.006	TC133UF.314.010
1.204.025	38.204.016	C1SXN.204.014	H1SEB.205.008	TC134.314.014
1.204.027	38.204.018	C1SXN.204.016	H1SEB.205.010	TC134F.314.014
1.204.029	38.204.021	C1SXN.204.018	H1SEB.205.012	TC134S.314.014
1.204.031	38.204.023	C1SXN.204.021	H1SEB.205.014	TC134UF.314.014
1.204.033	C1.204.006	C1SXN.204.023	H1SEB.206.004	TC135.314.014
1.204.035	C1.204.008	C1SXN.205.010	H1SEB.206.006	TC135F.314.014
1.204.037	C1.204.010	C1SXN.205.014	H1SEB.206.008	TC135S.314.014
1.204.040	C1.204.012	C1SXN.205.018	H1SEB.206.010	TC135UF.314.014
2.204.006	C1.204.014	C1SXN.205.023	H1SEB.206.012	TC152N.316.009
2.204.007	C1.204.016	C2.204.008	H1SEB.206.014	TC246.204.009
2.204.008	C1.204.018	C2.204.010	H1SNL.206.006	TC246.204.010
2.204.009	C1.204.021	C2.204.012	H1SNL.206.008	TC246.204.012
2.204.010	C1.204.023	C2.204.014	H1SNL.206.010	TC246.314.009
2.204.012	C1.204.027	C2.204.016	H1SNL.206.012	TC246.314.010
2.204.014	C1S.204.010	C2.204.018	H2.314.006	TC246.314.012
2.204.016	C1S.204.012	C21.204.010	H2.314.008	TC246L.314.012
2.204.018	C1S.204.014	C21.204.012	H2.314.010	TC246LUF.314.012
2.204.021	C1S.204.016	C21.204.014	H2.314.014	TC246UF.314.009
2.204.023	C1S.204.018	C21.204.016	H21.314.009	TC247.314.007
207.204.010	C1S.204.021	C21L.204.010	H21.314.010	TC247.314.009
207.204.012	C1S.204.023	C21R.204.010	H21.314.012	TC247.314.010
207.204.014	C1S.204.025	C21R.204.012	H21R.314.008	TC247.314.012
207.204.016	C1S.204.027	C22AGK.204.016	H21R.314.010	TC247F.314.007
21.204.008	C1S.204.029	C22AGK.314.016	H21R.314.012	TC247F.314.009
21.204.009	C1S.205.012	C22ALGK.205.016	H23.314.008	TC247F.314.010
21.204.010	C1S.205.014	C22ALGK.315.016	H23.314.009	TC247UF.314.007
21.204.012	C1S.205.016	C22GK.314.016	H23.314.010	TC247UF.314.009
21.204.014	C1S.205.018	C23.204.008	H23L.314.009	TC247UF.314.010
21.204.016	C1S.205.021	C23.204.010	H23L.314.010	TC248.314.009
21.204.018	C1S.205.023	C23.204.014	H23L.314.012	TC248.314.012
21.204.021	C1S.314.006	C23R.204.012	H245.314.008	TC275.314.010
21.204.023	C1S.314.007	C23R.204.014	H245PC.314.008	TC275.314.012
23.204.008	C1S.314.008	C23R.204.016	H31.314.009	TC280.314.009
23.204.009	C1S.314.009	C31.204.010	H31.314.010	TC281K.314.012
23.204.010	C1S.314.010	C31.204.012	H31.314.012	TC282.204.010
23.204.012	C1S.314.012	C31.204.014	H31PC.314.010	TC282.204.012
23.204.014	C1S.314.014	C31.204.018	H31R.314.010	TC282.314.009
23.204.016	C1S.314.016	C31R.204.012	H31R.314.012	TC282.314.010
23.204.018	C1S.314.018	C34.314.010	H31RPC.314.010	TC282.314.012
23.204.021	C1S.314.021	C34.314.012	H31RPC.314.012	TC282K.204.014
23.204.023	C1S.314.023	C34L.315.010	H33.314.009	TC282K.204.016
3.204.006	C1S.316.010	C34L.315.012	H33.314.010	TC282K.314.014
3.204.007	C1S.316.012	C34LT.315.012	H33.314.012	TC282K.314.016
3.204.008	C1S.316.014	C34LT.315.016	H33.314.016	TC283.204.012
3.204.009	C1S.316.016	C35L.315.012	H33L.314.009	TC283.314.010
3.204.010	C1S.316.018	C36RS.314.012	H33LGK.314.009	TC283.314.012
3.204.012	C1S.316.021	C4AK.314.010	H7.314.006	TC283.314.014
3.204.014	C1S.316.023	C4AK.314.012	H7.314.008	TC283K.204.016
3.204.016	C1S.317.010	C4AKL.315.012	H7.314.010	TC283K.204.021
3.204.018	C1S.317.014	C4AKXL.315.014	H7.314.012	TC283K.314.016
3.204.021	C1S.317.018	C4AKXXL.315.014	H7PC.314.008	TC283K.314.021
3.204.023	C1SDR.204.014	C7.204.012	T21X.314.010	TC284.204.014
36.204.006	C1SDR.204.016	C7L.204.010	T21X.314.012	TC284.314.014
36.204.007	C1SDR.204.018	C7L.204.012	T21XR.204.012	TC284K.314.018
36.204.008	C1SX.204.010	C7L.204.014	T21XR.314.010	TC284KN.316.016
36.204.009	C1SX.204.012	H1.314.005	T21XR.314.012	TC297.314.012
36.204.010	C1SX.204.014	H1.314.006	T23XR.314.012	TC297.314.014

TC30.314.006	TC41N.316.023	4027RA-6
TC30.314.008	TC41UF.204.018	4037RA-100
TC30.314.009	TC41UF.314.018	4037RA-6
TC30.314.010	TC46.204.012	4038RA-6
TC30.314.012	TC46.204.014	4039RA-6
TC30.314.014	TC46.204.018	C269GK.316.016
TC300.314.014	TC46.204.023	C269GK.317.016
TC300.314.021	TC46.314.012	C269GKS.314.016
TC336.314.016	TC46.314.014	C560.317.008
TC375.314.012	TC46.314.018	
TC375.314.014	TC46.314.023	
TC375.314.016	TC46N.316.014	
TC375R.314.012	TC47.314.010	
TC375R.314.014	TC47.314.014	
TC375R.314.016	TC47.314.018	
TC375R.314.018	TC47L.314.010	
TC375R.314.023	TC47L.314.012	
TC377.314.010	TC47L.314.014	
TC377.314.012	TC47L.314.016	
TC378.314.014	TC48L.314.010	
TC378.314.016	TC48L.314.012	
TC378N.316.014	TC48L.317.014	
TC379.204.012	TC48L.317.023	
TC379.204.014	TC48LF.314.012	
TC379.204.018	TC48LS.314.012	
TC379.204.023	TC48LUF.314.012	
TC379.314.012	TC48LUF.317.014	
TC379.314.014	TC48LUF.317.023	
TC379.314.018	TC49.314.010	
TC379.314.023	TC49.314.012	
TC379.317.014	TC49.314.014	
TC379.317.023	TC50.204.010	
TC379F.314.023	TC50.314.010	
TC379G.314.023	TC50.314.018	
TC379GK.314.014	TC50A.314.010	
TC379N.316.023	TC50AF.314.010	
TC379S.314.023	TC50AUF.314.010	
TC379UF.204.018	TC747.205.010	
TC379UF.204.023	TC747L.206.010	
TC379UF.314.014	TC758.204.012	
TC379UF.314.018	TC758L.206.012	
TC379UF.314.023	TC847KRG.314.016	
TC379UF.317.014	TC856G.314.016	
TC379UF.317.023	2003-6	
TC390.204.014	2014-6	
TC390.204.016	2019-6	
TC390.204.018	6320-3	
TC390.314.014	6321-3	
TC390.314.016	6322-3	
TC390.314.018	6323-3	
TC390S.314.018	6324-3	
TC390UF.204.016	6325-3	
TC390UF.314.016	6326-3	
TC41.204.010	6327-3	
TC41.204.012	6330-3	
TC41.204.014	6331-3	
TC41.204.016	6332-3	
TC41.204.018	6333-3	
TC41.204.023	4005RA-100	
TC41.204.027	4005RA-6	
TC41.204.031	4019RA-100	
TC41.314.010	4019RA-6	
TC41.314.012	4023RA-100	
TC41.314.014	4023RA-6	
TC41.314.016	4024RA-100	
TC41.314.018	4024RA-6	
TC41.314.023	4026RA-100	
TC41.314.027	4026RA-6	
TC41.314.031	4027RA-100	

Declaration of conformity

Product family: **Instruments for surgery - burs**
Surgery Instruments tungsten carbide / Surgery Instruments steel / Surgery Instruments Ceramic

Technical-Documentation: **TD_1 / Produkt-Gruppe_04**

According to Regulation: **(EU) 2017/745**

Class / Rule: **Ila / 6**

Basis-UDI-DI: **++E31211341CT**

SRN: **LI-MF-000011937**

EMDN Code.: **L159007**

UMDNS-Nr.: **11-341 (Bohrer, MKG-Chirurgie)**


Purpose-Determination:

For use in dental practice for users with appropriate qualifications (dental studies). Surgical instruments are precision instruments with high cutting ability and service life. They are universally suitable for removing and smoothing bone surfaces as well as for separating teeth and effectively chipping tooth structure as well as for separating tooth roots. The surgical instruments are offered in different shapes and designs.

We, Edenta Etablissement as manufacturer, hereby declare under our sole responsibility that the medical devices described above and the associated technical documentation comply with Regulation (EU) 2017/745 and all relevant national legislation.

The conformity assessment procedure applied corresponds to: Annex IX, taking into account the applicable harmonized standards and the (GS) Common Specifications, and verified with certificate ID-no. **1000183128**.

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main.

Identification-No.:  0297

Validity of the declaration of conformity: For all batches produced from the date of issue until March 27, 2030 (expiry date of the issued certificates).

The products are not sold sterile.

**Edenta Etablissement,
Industriestrasse 13
LI-9486 Schaanwald**

Schaanwald, 18.09.2025

A handwritten signature in blue ink, appearing to read "Meinrad Schreiber".

Meinrad Schreiber
Produkt Management

C141AC.104.023	C141.206.025	C267.316.016	229.205.040
C141AC.104.027	C141.206.027	C267.317.016	229.205.050
C141AC.104.031	C141.206.029	C269GKS.314.016	229.205.060
C141AC.104.035	C141.206.031	C269GK.316.016	229.205.080
C141AC.104.040	C141.206.035	C269GK.317.016	81IK.206.030
C141AC.104.050	C141.206.040	C269.104.016	81IK.206.040
C141AC.205.023	C141.206.050	C269.206.016	
C141AC.206.023	C141.207.027	C269.316.016	
C141A.104.023	C141.316.010	C269.317.016	
C141A.104.027	C141.316.012	C560.317.008	
C141A.104.031	C141.316.014	D254.317.016	
C141A.104.035	C141.316.016	GSD1.104.021	
C141A.104.040	C141.316.018	GSD1.104.023	
C141A.104.050	C141.316.021	GSD1.204.018	
C141A.205.023	C141.316.023	GSD1.204.021	
C141A.205.027	C151.316.015	GSD1.204.023	
C141A.205.031	C151.317.015	GSD1.314.016	
C141A.205.035	C157.316.011	GSD1.314.018	
C141A.205.040	C157.316.016	GSD1.314.021	
C141A.205.050	C161.104.016	G254.317.014	
C141A.206.023	C161.205.016	RFA.316.016	
C141A.206.027	C161.206.016	RFB.316.016	
C141A.206.031	C161.316.016	RFC.316.016	
C141A.206.035	C162A.104.016	RF161.104.016	
C141A.206.040	C162A.206.016	RF161.205.016	
C141A.206.050	C162A.316.016	RF161.316.016	
C141AC.205.027	C162A.317.016	RF162.104.016	
C141AC.205.031	C162AC.316.016	RF162.205.016	
C141AC.205.035	C162AAC.316.016	RF162.316.016	
C141AC.205.040	C162AAC.317.016	RF163.104.014	
C141AC.206.027	C162S.104.016	RF163.205.014	
C141AC.206.031	C162S.206.016	RF164.104.018	
C141AC.206.035	C162S.316.016	RF164.205.018	
C141AC.206.040	C162SAC.316.016	RF165.104.023	
C141.104.010	C162.104.016	RF165.205.023	
C141.104.014	C162.205.016	RF166.104.021	
C141.104.018	C162.206.016	RF166.205.021	
C141.104.023	C162.316.016	RF167.104.023	
C141.104.025	C163A.104.014	RF167.205.023	
C141.104.027	C163A.205.014	RF168.105.023	
C141.104.029	C166A.104.021	RF168.206.023	
C141.104.031	C166A.206.021	RF169.106.023	
C141.104.035	C166.104.021	STT249.314.016	
C141.104.040	C166.205.021	STT250.314.016	
C141.104.050	C166SAC.104.021	167IK.204.023	
C141.105.027	C166.206.021	186RF.104.018	
C141.105.029	C167.104.023	186RF.204.018	
C141.105.031	C167.206.023	210IK.16.204.020	
C141.105.035	C254A.104.012	210IK.16.204.028	
C141.105.040	C254A.205.012	210IK.19.205.020	
C141.105.050	C254A.206.012	210IK.19.205.028	
C141.205.010	C254A.316.012	210L.16.204.020	
C141.205.014	C254A.317.012	210L.16.204.028	
C141.205.018	C254AAC.316.012	210L.20.205.020	
C141.205.023	C254AAC.317.012	210L.20.205.028	
C141.205.025	C254.316.010	229L.205.030	
C141.205.027	C254.316.012	229L.205.035	
C141.205.029	C254.317.010	229L.205.040	
C141.205.031	C254.317.012	229L.205.045	
C141.205.035	C255A.104.012	229L.205.050	
C141.205.040	C255A.206.012	229L.205.060	
C141.205.050	C255A.317.012	229L.205.070	
C141.206.010	C262.104.016	229L.205.080	
C141.206.014	C262.206.016	229.205.025	
C141.206.018	C262.316.016	229.205.030	
C141.206.023	C262.317.016	229.205.035	

Declaration of conformity

Product family: **Drilling instruments, root canal**

Gates / Peeso / Root Canal reamer / Endodontic-drill / Nerve broaches / K-Reamer / „K“
- Files / Hedström Files / NiTi Files / root fillers „L“ / Endo Stops

Technical-
Documentation: **TD_1 / Produkt-Gruppe_07**

According
to Regulation: **(EU) 2017/745**

Class / Rule: **Ila / 6**

Basis-UDI-DI: **++E31216411DS**

SRN: **LI-MF-000011937**

EMDN Code.: **L159004**

UMDNS-Nr.: **16-411 (Root canal instruments - roating)**


Purpose-Determination:

For use in dental practice for users with appropriate qualifications (dental studies). Root canal instruments are used for root canal preparation (removal of damaged, infected or dead tooth pulp).

We, Edenta Etablissement as manufacturer, hereby declare under our sole responsibility that the medical devices described above and the associated technical documentation comply with Regulation (EU) 2017/745 and all relevant national legislation.

The conformity assessment procedure applied corresponds to: Annex IX, taking into account the applicable harmonized standards and the (GS) Common Specifications, and verified with certificate ID-no. **1000183128**.

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main.

Identification-No.:  0297

Validity of the declaration of conformity: For all batches produced from the date of issue until March 27, 2030 (expiry date of the issued certificates).

The products are not sold sterile.

**Edenta Etablissement,
Industriestrasse 13
LI-9486 Schaanwald**

Schaanwald, 18.09.2025



Meinrad Schreiber
Produkt Management

171.21.654.008	173.21.654.015	174.21.654.025	178.25.204.035
171.21.654.010	173.21.654.020	174.21.654.030	178.25.204.040
171.21.654.015	173.21.654.025	174.21.654.035	178.25.204SO
171.21.654.020	173.21.654.030	174.21.654.040	178S.21.204.025
171.21.654.025	173.21.654.035	174.21.654.045	178S.21.204.030
171.21.654.030	173.21.654.040	174.21.654.050	178S.21.204.035
171.21.654.035	173.21.654.045	174.21.654.055	178S.21.204.040
171.21.654.040	173.21.654.050	174.21.654.060	178S.21.204SO
171.21.654.045	173.21.654.055	174.21.654.070	178S.25.204.025
171.21.654.050	173.21.654.060	174.21.654.080	178S.25.204.030
171.21.654.055	173.21.654.070	174.21.654SO1	178S.25.204.035
171.21.654.060	173.21.654.080	174.21.654SO2	178S.25.204.040
171.21.654.070	173.21.654SO1	174.25.654.008	178S.25.204SO
171.21.654.080	173.21.654SO2	174.25.654.010	180.15.204.050
171.21.654SO1	173.25.654.008	174.25.654.015	180.15.204.070
171.21.654SO1	173.25.654.010	174.25.654.020	180.15.204.090
171.25.654.008	173.25.654.015	174.25.654.025	180.15.204.110
171.25.654.010	173.25.654.020	174.25.654.030	180.15.204.130
171.25.654.015	173.25.654.025	174.25.654.035	180.15.204.150
171.25.654.020	173.25.654.030	174.25.654.040	180.15.204SO
171.25.654.025	173.25.654.035	174.25.654.045	180.19.204.050
171.25.654.030	173.25.654.040	174.25.654.050	180.19.204.070
171.25.654.035	173.25.654.045	174.25.654.055	180.19.204.090
171.25.654.040	173.25.654.050	174.25.654.060	180.19.204.110
171.25.654.045	173.25.654.055	174.25.654.070	180.19.204.130
171.25.654.050	173.25.654.060	174.25.654.080	180.19.204.150
171.25.654.055	173.25.654.070	174.25.654SO1	180.19.204SO
171.25.654.060	173.25.654.080	174.25.654SO2	183.15.204.070
171.25.654.070	173.25.654SO1	174.28.654.008	183.15.204.090
171.25.654.080	173.25.654SO2	174.28.654.010	183.15.204.110
171.25.654SO1	173.28.654.008	174.28.654.015	183.15.204.130
171.25.654SO2	173.28.654.010	174.28.654.020	183.15.204.150
171.28.654.008	173.28.654.015	174.28.654.025	183.15.204.170
171.28.654.010	173.28.654.020	174.28.654.030	183.15.204SO
171.28.654.015	173.28.654.025	174.28.654.035	183.19.204.070
171.28.654.020	173.28.654.030	174.28.654.040	183.19.204.090
171.28.654.025	173.28.654.035	174.28.654.045	183.19.204.110
171.28.654.030	173.28.654.040	174.28.654.050	183.19.204.130
171.28.654.035	173.28.654.045	174.28.654.055	183.19.204.150
171.28.654.040	173.28.654.050	174.28.654.060	183.19.204.170
171.28.654.045	173.28.654.055	174.28.654.070	183.19.204SO
171.28.654.050	173.28.654.060	174.28.654.080	9107.11.654.020
171.28.654.055	173.28.654.070	174.28.654SO1	9107.11.654.025
171.28.654.060	173.28.654.080	174.28.654SO2	9107.11.654.030
171.28.654.070	173.28.654SO1	174.31.654.008	9107.11.654.035
171.28.654.080	173.28.654SO2	174.31.654.010	9107.11.654.040
171.28.654SO1	173.31.654.008	174.31.654.015	9107.11.654.050
171.28.654SO2	173.31.654.010	174.31.654.020	9107.11.654.060
171.31.654.008	173.31.654.015	174.31.654.025	9107.11.654SO1
171.31.654.010	173.31.654.020	174.31.654.030	ST-10.35
171.31.654.015	173.31.654.025	174.31.654.035	NT-04.20
171.31.654.020	173.31.654.030	174.31.654.040	NT-04.25
171.31.654.025	173.31.654.035	174.31.654.045	NT-04.30
171.31.654.030	173.31.654.040	174.31.654.050	NT-04.35
171.31.654.035	173.31.654.045	174.31.654.055	NT-06.20
171.31.654.040	173.31.654.050	174.31.654.060	NT-06.25
171.31.654.045	173.31.654.055	174.31.654.070	NT-06.30
171.31.654.050	173.31.654.060	174.31.654.070	NT-06.35
171.31.654.055	173.31.654.070	174.31.654SO1	NT-901SO
171.31.654.060	173.31.654.080	174.31.654SO2	NT-902SO
171.31.654.070	173.31.654SO1	178.21.204.025	NT-903SO
171.31.654.080	173.31.654SO2	178.21.204.030	
171.31.654SO1	174.21.654.008	178.21.204.035	
171.31.654SO2	174.21.654.010	178.21.204.040	
173.21.654.008	174.21.654.015	178.21.204SO	
173.21.654.010	174.21.654.020	178.25.204.025	