

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, 25.11.2025



Meinrad Schreiber
Produkt Management

171.21.654.008	173.21.654.015	174.21.654.025	178.25.204.030
171.21.654.010	173.21.654.020	174.21.654.030	178.25.204.035
171.21.654.015	173.21.654.025	174.21.654.035	178.25.204.040
171.21.654.020	173.21.654.030	174.21.654.040	178.25.204SO
171.21.654.025	173.21.654.035	174.21.654.045	178S.21.204.025
171.21.654.030	173.21.654.040	174.21.654.050	178S.21.204.030
171.21.654.035	173.21.654.045	174.21.654.055	178S.21.204.035
171.21.654.040	173.21.654.050	174.21.654.060	178S.21.204.040
171.21.654.045	173.21.654.055	174.21.654.070	178S.21.204SO
171.21.654.050	173.21.654.060	174.21.654.080	178S.25.204.025
171.21.654.055	173.21.654.070	174.21.654SO1	178S.25.204.030
171.21.654.060	173.21.654.080	174.21.654SO2	178S.25.204.035
171.21.654.070	173.21.654SO1	174.25.654.008	178S.25.204.040
171.21.654.080	173.21.654SO2	174.25.654.010	178S.25.204SO
171.21.654SO1	173.25.654.008	174.25.654.015	180.15.204.050
171.21.654SO2	173.25.654.010	174.25.654.020	180.15.204.070
171.25.654.008	173.25.654.015	174.25.654.025	180.15.204.090
171.25.654.010	173.25.654.020	174.25.654.030	180.15.204.110
171.25.654.015	173.25.654.025	174.25.654.035	180.15.204.130
171.25.654.020	173.25.654.030	174.25.654.040	180.15.204.150
171.25.654.025	173.25.654.035	174.25.654.045	180.15.204SO
171.25.654.030	173.25.654.040	174.25.654.050	180.19.204.050
171.25.654.035	173.25.654.045	174.25.654.055	180.19.204.070
171.25.654.040	173.25.654.050	174.25.654.060	180.19.204.090
171.25.654.045	173.25.654.055	174.25.654.070	180.19.204.110
171.25.654.050	173.25.654.060	174.25.654.080	180.19.204.130
171.25.654.055	173.25.654.070	174.25.654SO1	180.19.204.150
171.25.654.060	173.25.654.080	174.25.654SO2	180.19.204SO
171.25.654.070	173.25.654SO1	174.28.654.008	183.15.204.070
171.25.654.080	173.25.654SO2	174.28.654.010	183.15.204.090
171.25.654SO1	173.28.654.008	174.28.654.015	183.15.204.110
171.25.654SO2	173.28.654.010	174.28.654.020	183.15.204.130
171.28.654.008	173.28.654.015	174.28.654.025	183.15.204.150
171.28.654.010	173.28.654.020	174.28.654.030	183.15.204.170
171.28.654.015	173.28.654.025	174.28.654.035	183.15.204SO
171.28.654.020	173.28.654.030	174.28.654.040	183.19.204.070
171.28.654.025	173.28.654.035	174.28.654.045	183.19.204.090
171.28.654.030	173.28.654.040	174.28.654.050	183.19.204.110
171.28.654.035	173.28.654.045	174.28.654.055	183.19.204.130
171.28.654.040	173.28.654.050	174.28.654.060	183.19.204.150
171.28.654.045	173.28.654.055	174.28.654.070	183.19.204.170
171.28.654.050	173.28.654.060	174.28.654.080	183.19.204SO
171.28.654.055	173.28.654.070	174.28.654SO1	9107.11.654.020
171.28.654.060	173.28.654.080	174.28.654SO2	9107.11.654.025
171.28.654.070	173.28.654SO1	174.31.654.008	9107.11.654.030
171.28.654.080	173.28.654SO2	174.31.654.010	9107.11.654.035
171.28.654SO1	173.31.654.008	174.31.654.015	9107.11.654.040
171.28.654SO2	173.31.654.010	174.31.654.020	9107.11.654.050
171.31.654.008	173.31.654.015	174.31.654.025	9107.11.654.060
171.31.654.010	173.31.654.020	174.31.654.030	9107.11.654SO1
171.31.654.015	173.31.654.025	174.31.654.035	ST-10.35
171.31.654.020	173.31.654.030	174.31.654.040	NT-04.20
171.31.654.025	173.31.654.035	174.31.654.045	NT-04.25
171.31.654.030	173.31.654.040	174.31.654.050	NT-04.30
171.31.654.035	173.31.654.045	174.31.654.055	NT-04.35
171.31.654.040	173.31.654.050	174.31.654.060	NT-06.20
171.31.654.045	173.31.654.055	174.31.654.070	NT-06.25
171.31.654.050	173.31.654.060	174.31.654.080	NT-06.30
171.31.654.055	173.31.654.070	174.31.654SO1	NT-06.35
171.31.654.060	173.31.654.080	174.31.654SO2	NT-901SO
171.31.654.070	173.31.654SO1	178.21.204.025	NT-902SO
171.31.654.080	173.31.654SO2	178.21.204.030	NT-903SO
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	