



EU Quality Management Certificate



This is to certify that the company

Edenta Etablissement

Industriestrasse 13
9486 Schaanwald
Liechtenstein

SRN: LI-MF-000011937

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	549934 MDR2017Q
Certificate ID	1000183128
Effective date	2025-03-27
Expiry date	2030-03-26
Frankfurt am Main,	2025-03-27



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: LI-MF-000011937
Certificate ID: 1000183128

Device categories and variants covered by this certificate:

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Polishers (Rubber/Arkansas stone) Group 1
Risk classification: IIa
Basic-UDI-DI: ++E31216412DU
Intended purpose: 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.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Burs dental diamond (Diamond burs) Group 2
Risk classification: IIa
Basic-UDI-DI: ++E31216670EL, ++E31263358FH
Intended purpose: 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.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Burs dental (Tungsten carbide- and steel burs / Finishing instruments) Group 3
Risk classification: IIa
Basic-UDI-DI: ++E31210521CQ
Intended purpose: 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.

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Burs MKG surgery (Instruments for surgery - burs) Group 4
Risk classification: IIa
Basic-UDI-DI: ++E31211341CT
Intended purpose: 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.



Annex to EU Quality Management Certificate
SRN of Manufacturer: LI-MF-000011937
Certificate ID: 1000183128

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Drilling instruments, root canal (root canal instruments + rotating)
Group 7
Risk classification: IIa
Basic-UDI-DI: ++E31216411DS
Intended purpose: 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).

Device category: **MDN 1208 - Non-active non-implantable instruments**
Product name: Drilling instruments, orthopedics (Instruments podology/footcare)
Group 8
Risk classification: IIa
Basic-UDI-DI: ++E31217761EX
Intended purpose: For use in podiatry practice for users with appropriate qualifications (podology course). Podiatry instruments (polishers, diamond grinders, carbide steel drill bits) are precision instruments with high cutting ability and service life. They are universally suitable for various preparations and the processing of many podiatric applications.

Examinations and tests performed:

549934_A215192MED_01 dated 2024-12-20

549934_A215193MED_02 Burs dental Group 3 dated 2025-03-17

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a