Manufacturers Name and Address:	**M.D.T Micro Diamond Technologies Ltd.** 2 Hamal st Afula 1857107, Israel TEL: + 972-4-6094422 FAX: + 972-4-6597812	
SRN (Single Registration Number):	IL-MF-000008464	
Authorized Representative Name and Address:	**OBELIS S.A** BD. GÉNÉRAL WAHIS 53 1030 BRUSSELS, BELGIUM TEL: + (32) 2. 732.59.54 FAX: +(32) 2.732.60.03 E-MAIL: MAIL@OBELIS.NET	
Basic UDI-DI:	*7291046DiamondSterileFM* *7291046DiamondnonStrlRE* *7291046DiscnonStrl5W* *7291046CarbideSterileYW* *7291046CarbidenonStrlAS* *7291046PolisherSterile3T* *7291046PolishernonStrlDL*	*Diamond coated burs, sterile* *Diamond coated burs, non-sterile* *Diamond coated discs, non-sterile* *Tungsten Carbide (TC) burs, sterile* *Tungsten Carbide (TC) burs, non-sterile* *Dental Polishers, sterile* *Dental Polishers, non-sterile*
Name of the Device (s):	**Dental Rotary Instruments**- Including: Diamond coated burs, sterile and non-sterile Diamond coated discs, non-sterile Tungsten Carbide (TC) burs, sterile and non-sterile. Dental Polishers, sterile and non-sterile	
Intended Purpose:	The Dental Rotary Instruments are intended for laboratory and dental applications in clinics and hospitals, both chair side and within the dental oral orifice.	
Product Listing and Trade Names:	Applicable product listing QTF 01.05.01	
Classification:	According to Annex VIII of the MDR 2017/745, the above-mentioned devices are classified as Class IIa, under Rules 5 and 6	
Relevant Standards:	Reference TF-000-Stand -MDT List of applicable standards	
Name and Address of Notified Body:	MDC medical device certification GmbH Kriegerstraße 6 / 70191 Stuttgart Phone: +49 711 253597-0 E-Mail: mdc@mdc-ce.de **Identification number:** 0483	
MDT CE Certificate:	CE 0483	EC Certificate no. D1066900021 valid until 08.08.2028 Quality System meets requirements according to Annex IX chapters I and III.
Conformity assessment route:	**MDT uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:** Class IIa: EC conformity declaration according to annex II + annex III Technical Documentation and according to annex IX chapters I and III Quality Management System and Assessment of Technical Documentation.	

This declaration of conformity is issued under the sole responsibility of MDT. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to EN ISO 13485:2016 + AC:2018 + A11:2021 – ISO 13485:2016 issued by MDC Medical Device Certification GmbH. All supporting documentation is retained at the premises of the manufacturer.	
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Pini Lahav Title: CTO QA RA Director, PRRC Signature:  Place of Issue: Afula, Israel Date: 09.08.2023
Validity	08.08.2028