

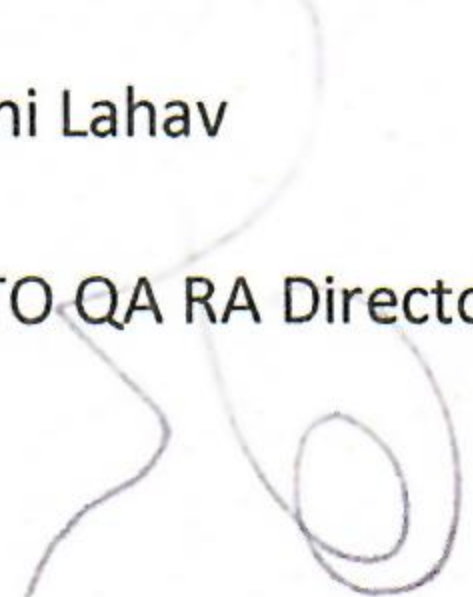


Title:	Declaration of Conformity – MDT's Dental Rotary Instruments	
Doc #: TF-000- DOC	Rev: 20	Effective Date: 15.4.2021
Page 1 of 1	Owner: TF/RA	Technical File Document

Identification of the Legal Manufacturer:	 <p>M.D.T Micro Diamond Technologies Ltd. 2 Hamal st Industrial park Afula 1857107, Israel TEL: + 972-4-6094422 FAX: + 972-4-6597812</p>
Identification of Authorized Representative:	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">EC</div> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">REP</div> </div> <p>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</p>
Declare on our own responsibility that: - our products " MDT Dental Rotary Instruments " fulfills the requirements of the MDD-Medical Device Directive - our quality system and production meet the requirements of the EC Council Directive 93/42 EEC, Annex V - our quality system is in compliance with MDR 2017/745 Article 120 Section 3 and Article 10 requirements.	
Identification of the device(s) concerned:	<p><i>Diamond coated burs, sterile and non-sterile</i></p> <p><i>Diamond coated discs, non-sterile</i></p> <p><i>Tungsten Carbide (TC) burs, sterile and non-sterile.</i></p> <p><i>Dental Polishers, sterile and non-sterile</i></p> <p><i>Applicable product listing QTF 01.05.01</i></p>
Classification:	According to Annex IX of the above directive, the above-mentioned devices are classified as Class IIa, under Rules 5 and 6
Relevant Standards	Reference QTF-01.04.01 MDT List of Applicable Standards
Name and address of Notified Body:	<p>MDC medical device certification GmbH Kriegerstraße 6 / 70191 Stuttgart Phone: +49 711 253597-0 E-Mail mdc@mdc-ce.de Identification number: 0483</p>
MDT CE Certificate(s):	<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;">  <div style="font-size: 24px; font-weight: bold;">0483</div> </div> <div> <p>EC Certificate no. D1066900019 valid until 28.8.2023</p> <p>Quality System meets requirements according to Annex V Section 3</p> </div> </div>
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p>Name: Pini Lahav</p> <p>Title: CTO QA RA Director, PRRC</p> <p>Signature: </p> <p>Place of Issue: Afula, Israel</p> <p>Date: April 15, 2021</p>
Validity	28.8.2023 (unless affected by changes)