

Declaration of Conformity

Manufacturer's Name: Dental Imaging Technologies Corporation

Manufacturer's Address: 1910 North Penn Rd.
Hatfield, PA 19440
United States

I hereby declare, under our sole responsibility as the Manufacturer, that the products listed on this schedule meet the provisions of the Medical device Directive 93/42/EEC as amended by 2007/47/EC and transposed into Swedish law by Statutory Instrument LVFS 2003:11.

I further declare that products are Class IIa per Rule 16 and are not supplied Sterile and that our conformance route is Annex II.


This declaration is valid for product manufactured from February 20, 2020.

Our Notified Body is SEMKO and their notified number is 0413.

Authorized Representative: Kaltenbach & Voigt GmbH
Bismarckring 39
88400 Biberach
Germany
Tel: +49 (7351) 56 - 0
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Model Numbers: See table below.

Device	Model #
DEXIS Titanium	1.012.6180
KaVo IXS Size 1	1.012.6181
KaVo IXS Size 2	1.012.6182

Signature:  at (Hatfield, PA) Date: 02/20/2020
Sr. Manager, Regulatory Affairs