EU Declaration of Conformity

We, the manufacturer

Dental Imaging Technologies Corporation
450 Commerce Drive
Quakertown, PA 18951
U.S.A.
SRN: US-MF-000017139

certify the device(s) listed in the table below conform(s) with the provisions according to the regulation on medical devices, EU 2017/745, the Swedish national legislation LVFS 2003:11, Electromagnetic Compatibility Directive 2004/108/EC, RoHS 3 Directive 2015/863 amending Annex II to Directive 2011/65/EU of the European Parliament, and RoHS 2 Directive 2011/65/EU.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Description	NAME	REF	Basic UDI-DI	Risk Class
System, X-Ray, Extraoral Source, Digital	DEXIS Titanium	1.012.6180	++D090Polaris5J	Class IIa, Rule 17 of Annex VIII
	DEXIS IXS Size 1	1.012.6181		
	DEXIS IXS Size 2	1.012.6182		

Products may be sold separately or distributed in convenience kits. Kit Model Numbers:

Kit	Model #	Basic UDI-DI
DEXIS IXS S1 Kit, EN FR IT DE ES NL PT	1.013.9716	++D090Polaris5J
DEXIS IXS S1 Kit, RO SK PL GR RU CZ HU	1.013.9717	
DEXIS IXS S1 Kit, SV DA EE NO LV LT TR	1.013.9718	
DEXIS IXS S1 Kit, EN CN JA BG HR SI	1.014.6104	
DEXIS IXS S2 Kit, EN FR IT DE ES NL PT	1.013.9719	
DEXIS IXS S2 Kit, RO SK PL GR RU, CZ, HU	1.013.9720	
DEXIS IXS S2 Kit, SV DA EE NO LV LT TR	1.013.9721	
DEXIS IXS S2 Kit, EN CN JA BG HR SI	1.014.6105	
DEXIS DX Titan Kit, EN FR IT DE ES NL PT	1.014.5207	
DEXIS DX Titan Kit, RO SK PL GR RU CZ HU	1.014.5209	
DEXIS DX Titan Kit, SV DA EE NO LV LT TR	1.014.5210	
DEXIS DX Titan Kit, EN CN JA BG HR SI	1.014.6147	

Product warranty and replacement model numbers:

Device	Model #	Basic UDI-DI
DEXIS Titanium Warranty Replacement New	1.013.7049	++D090Polaris5J
DEXIS IXS S1 Warranty New	1.013.9722	
DEXIS IXS S2 Warranty New	1.013.9723	

Standards/Common Specifications	Year & Edition
EN 60601-1	2006+A1:2013
IEC 60601-1	2005 Ed.3+C1;C2;A1:2012
IEC 60601-1	1988 + A1:1991+A2:1995 (2nd Ed.)
IEC 60601-1-2	2014 (4th Ed)
IEC 60601-1-2	2007 (3rd Ed.)
IEC 60601-1-4	2000
IEC 60601-1-6	2010, AMD1:2013
IEC 60601-1-6	2004
IEC 60601-2-65	2012
IEC 62366	2007, AMD1:2014
IEC 62304	2006 Ed.1 +A1:2015
EN-ISO 13485	2016
ISO 14971	2007
EN ISO 14971	2012
ANSI/AAMI ES60601-1	2005 +AC1+A2:2012
ISO 10993-1	2018

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Intended purpose: The DEXIS intraoral sensors is a USB-driven digital sensor which is intended to acquire dental intraoral radiographic images. The sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.

Authorized Representative: PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, FINLAND
Email: regulatory@dexis.com
SRN: FI-AR-000004955

Notified Body: Intertek Medical Notified Body AB 2862
Torshamnsgatan 43, Box 1103
SE-164 22 Kista, Sweden

EC Certificate: 28620207228

Conformity Assessment: Regulation on medical devices, EU 2017/745, Chapters I and III of Annex IX (Quality Management System and on Assessment of Technical Documentation), and section 4 of that Annex.

Quality System Certificate: Dental Imaging Technologies Corporation
Certificate Number: 0055228-00-11
GMDN Code and Term: 44905 / Dental digital imaging sensor, intraoral
EMDN Code and Term: Z1103040102 / Equipment for Digital Endoral Radiology

DocuSigned by:
PETER SCHMIDT
CF9624C2E95E498...
Peter Schmidt
Senior Regulatory Affairs Specialist
Dental Imaging Technologies Corporation

14-May-2025 | 12:20 EDT
Date