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 with the provisions according to the regulation on medical devices, EU 2017/745, the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2011/65 EU (RoHS 2) and Directive 2015/863 EU (RoHS 3), the Radio Equipment Directive [Directive 2014/53/EU] and the EU Batteries Regulation 2023/1542,(Directive 2014/53/EU, and Regulation EU 2023/1542 is only applicable to IS3800W and DEXIS Imprevo).

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

Description	Name	REF	Basic UDI-DI	Risk Class
Intraoral Scanner	IS 3600 I/O 3D Scanner	6568745	0693856IOSGU	Class I, Rule 5, Annex VIII
Intraoral Scanner	IS 3700 I/O 3D Scanner	5941307		Class I, Rule 5, Annex VIII
Intraoral Scanner	IS 3800W I/O 3D Scanner	5943063		Class I, Rule 5, Annex VIII
Intraoral Scanner	IS 3800 I/O 3D Scanner	5943725		Class I, Rule 5, Annex VIII
Intraoral Scanner	DEXIS Imprevo	5945148		Class I, Rule 5, Annex VIII
Accessory	IS 3600 NORMAL TIP 5 PCS	6569560	0693856IOSGU	Class I, Rule 5, Annex VIII
Accessory	IS 3600 SIDE TIP 5 PCS	6569552		Class I, Rule 5, Annex VIII
Accessory	IS 3600 POSTERIOR TIP 5 PCS	6577894		Class I, Rule 5, Annex VIII
Accessory	IS 3700 NORMAL TIP 5 PCS	5942156		Class I, Rule 5, Annex VIII
Accessory	IS 3700 SIDE TIP 5 PCS	5942172		Class I, Rule 5, Annex VIII
Accessory	IS 3700 POSTERIOR TIP 5 PCS	5942164		Class I, Rule 5, Annex VIII
Accessory	IS 3800 NORMAL TIP 5 PCS	5943659		Class I, Rule 5, Annex VIII
Accessory	IS 3800 SIDE TIP 5 PCS	5943667		Class I, Rule 5, Annex VIII
Accessory	IS 3800 POSTERIOR TIP 5 PCS	5943675		Class I, Rule 5, Annex VIII
Accessory	DEXIS Imprevo TIP 5 PCS	5945149		Class I, Rule 5, Annex VIII

Standard	Description	Model
EN ISO 13485: 2016/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN ISO 14971: 2019	Medical devices – Application of risk management to medical devices	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN ISO 15223-1: 2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirement	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 60601-1: 2006 / A1: 2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests	3600, 3700, 3800, 3800W, DEXIS Imprevo
IEC 60601-1-6: 2010 / A1: 2013 / A2:2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	3600, 3700, 3800, 3800W, DEXIS Imprevo
IEC 62366-1: 2015 / A1: 2020	Medical Devices – Part 1: Application of usability engineering to medical devices	3600, 3700, 3800, 3800W, DEXIS Imprevo

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IEC 62304: 2006 / A1: 2015	Medical device software — Software life cycle processes	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 62471: 2008	Photobiological safety of lamps and lamp systems	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 63000: 2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN ISO 17664-1: 2021	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 60601-2-18:2015	Medical Electrical Equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	3600, 3700, 3800, 3800W DEXIS Imprevo
EN 301 489-1 V2.2.3: 2019	Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU	3800W DEXIS Imprevo
EN 301 489-17 V3.2.4: 2020	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU	3800W DEXIS Imprevo
EN 301 893 V2.1.1: 2017	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	3800W DEXIS Imprevo
EN 62133: 2013	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	3800W
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer	3600, 3700, 3800, 3800W, DEXIS Imprevo
EN 62133-2:2017+A1:2021	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications − Lithium systems	DEXIS Imprevo
EN 50566: 2017	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body.	3800W DEXIS Imprevo
EN 62353:2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment	3600, 3700, 3800, 3800W, DEXIS Imprevo
IEC 60825-1: 2014	Safety of laser products − Equipment classification and requirements	DEXIS Imprevo

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Intended Purpose: The IS 3600, IS 3700, IS 3800, IS 3800W and DEXIS Imprevo are digital optical scanning devices used to record the topographic characteristics of teeth or dental impressions in three dimensions. The resulting topographic impressions are intended for use in the computer-aided design and manufacturing of dental restorative prosthetic devices, dental implant prosthetic devices, and orthodontic models.

Authorized Representative: PaloDEx Group Oy
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Tel: +358 10 2702000
Email: regulatory@dexis.com
SRN: FI-AR-000004955

EC Certificate: Not applicable

Quality System Certificate: Dental Imaging Technologies Corporation
Certificate Number: 0055228-00-10

GMDN Code and Term: 63669 / Intraoral optical scanning system
EMDN Code and Term: Z12110101 / Dental Treatment Units

Jinyao Huang
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Name: Jinyao Huang
Title: Compliance Manager, RAQA

09-Jan-2025 | 00:54 PST
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Date