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DOCUMENT TITLE:	IOS Scanners DoC
DOCUMENT NOTES:	

Controlled Document

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EU Declaration of Conformity

We, the manufacturer

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certify the device(s) listed in the table below conform with Annex I, General Safety and Performance Requirements, and Annex IV, EU Declaration of Conformity of the Regulation EU 2017/745 of the European Parliament and of the Council on Medical Device, Article 4 of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2011/65 EU, and ANNEX II of the Radio Equipment Directive [Directive 2014/53/EU] (Directive 2014-53/EU is only applicable to the 3800W).

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

Standard	Description	Model
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes	3600, 3700, 3800W
EN ISO 14971: 2019	Medical devices – Application of risk management to medical devices	3600, 3700, 3800W
EN ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirement	3600, 3700, 3800W
EN 1041: 2008	Information supplied by the manufacturer of medical devices	3600, 3700, 3800W
EN 60601-1: 2006 / A1: 2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	3600, 3700, 3800W
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, 3800W
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, 3800W
IEC 62366-1: 2015 / A1: 2020	Medical Devices – Part 1: Application of usability engineering to medical devices	3600, 3700, 3800W
IEC 62304: 2006 / A1: 2015	Medical device software — Software life cycle processes	3600, 3700, 3800W
EN 62471: 2008	Photobiological safety of lamps and lamp systems	3600, 3700, 3800W
EN ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	3600, 3700, 3800W
EN 63000: 2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	3600, 3700, 3800W
EN ISO 17664: 2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	3600, 3700, 3800W
EN 60601-2-18:2015	Medical Electrical Equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	3800W

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EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances	3800W
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
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
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
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 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

Intended Purpose: The IS 3600, IS 3700, and IS 3800 Wireless 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.

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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

This declaration is valid for product manufactured on or after September 14, 2022.

PETER SCHMIDT

Name: Peter Schmidt
Title: Senior Regulatory Affairs Specialist

September 14, 2022
Date

Signature Manifest

Document Number: ISI-DoC-031 **Revision:** F
Title: IOS Scanners DoC

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ISI-DoC-031

Approval

Name/Signature	Title	Date	Meaning/Reason
Erika Martin (ERIKA.MARTIN)	Sr.Global RA Manager Imaging	14 Sep 2022, 03:15:14 PM	Approved

Notify Orginator - Release

Name/Signature	Title	Date	Meaning/Reason
Peter Schmidt (PETER.SCHMIDT)	Kavo Sr. RA Specialist	14 Sep 2022, 03:15:14 PM	Email Sent