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7. EC Declaration of Conformity

(Rev. 3)

Intraoral Camera

(Model: Planmeca Somia

Variant model: KaVo ProXam iCam)

	NAME / SIGNATURE	DATE
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REVIEWED BY:	Sunjoon Park 	2021-05-06
APPROVED BY	Jonghyuk, Lee 	2021-05-06

Document Revision History

Rev. No.	Date	Revision Clause	Revision Details	Approval	
1	2018-07-08	None	Initial in accordance with 93/42/EEC+2007/47/EC	Prepared by	(sign)
				Reviewed by	(sign)
				Approved by	(sign)
2	2021-05-06	All	Revision in accordance with (EU)2017/745	Prepared by	Sunjoon Park
				Reviewed by	Sunjoon Park
				Approved by	Jonghyuk, Lee
3	2022-11-28	All	Revised according to the addition of a variant model	Prepared by	Sunjoon Park
				Reviewed by	Sunjoon Park
				Approved by	Jonghyuk, Lee
				Prepared by	(sign)
				Reviewed by	(sign)
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EU Declaration of Conformity

Manufacturer:
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EC Representative:
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Product Name: **Intraoral Camera**
Model : **Planmeca Somia**
Variant Model: **KaVo ProXam iCam (Kabel 1,3m/ 2,5m)**
GMDN Code: **63672**
SRN: **KR-MF-000013640**
Basic UDI-DI: **88000969IOC01LG**
Classification: **Class I (According to Rule 13 of (EU)2017/745, Annex VIII)**
Reference to Technical Documentation: **TCF-IC05-0 (Rev.2)**
Reference Standard (Including CS): **See the next pages (Appendix I)**
Intended Purpose: Non-diagnostic intraoral camera used by dentists to illuminate and magnify dental surfaces

We hereby declare that the device is in conformity with the (EU) 2017/745 and with any other relevant union legislation that provides for the issuing of an EU declaration of conformity. The device has been designed and manufactured under a quality management system according to Annex IX (excluding chapter 2 and 3) of (EU) 2017/745.

CE

The above mentioned declaration of conformity is issued under the sole responsibility of Dentall Co., Ltd.

Bucheon-si Korea	2022-11-07	Name: PRRC *Jonghyuk Lee*
Place	*Date*	*Legally binding signature, Function*

Appendix I. Reference Standards

No.	Standard or Guidance	Title
1	(EU) 2017/745 + Amd. (EU)2020/561	Medical Device Regulation
2	EN ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
3	EN ISO 14971:2019 (ISO 14971:2019)	Medical devices - Application of risk management to medical devices
4	EN ISO/TR24971:2020 (ISO/TR 24971:2020)	Medical devices - Guidance on the application of ISO 14971
5	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)	Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
6	EN 60601-1-2:2015 (IEC 60601-1-2:2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
7	EN 60601-1-6:2010/A1:2013 (IEC 60601-1-6:2010/A1:2015)	Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
8	IEC 60529:1989/AMD2:2013	Degrees of protection provided by enclosures (IP Code)
9	EN 62366-1:2015 (IEC 62366-1:2015)	Medical devices - Application of usability engineering to medical devices
10	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes
11	EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
12	EN 80601-2-60:2015 (IEC 80601-2-60:2012)	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
14	2011/65/EU amended to 2015/863/EU	The restriction of the use of certain hazardous substances in electrical and electronic equipment
15	EN ISO 15223-1:2016 (ISO 15223-1:2016)	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

No.	Standard or Guidance	Title
16	MEDDEV 2.7.1 rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
17	MDCG 2020-5:2020	Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies
18	MDCG 2020-6:2020	Guidance on sufficient clinical evidence for legacy devices
19	MDCG 2020-7	Guidance on PMCF plan template
20	MDCG 2020-8	Guidance on PMCF evaluation report template
21	MDCG 2020-15	MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
22	MDCG 2018-4	Definitions/descriptions and formats of the UDI core elements for systems or procedure packs
23	MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI
24	MDCG 2019-2	Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017