IQ1 90096395 T221 V01

PLANMECA

Letter for Compliance

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product KaVo ProXam iOS is substantially equal with Planmeca Emerald S from a technical point of view and differ only in optical appearance.

Therefore, the Declarations of Conformity for Planmeca Emerald S, dated 6.9.2022 following the provisions of **Medical Device Regulation (EU) 2017/745** is also valid for the KaVo ProXam iOS.

Helsinki, 2023-05-02

Niina Vuorikallas
Director, Quality & Regulatory Affairs

PLANMECA

EU DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
FIN-00880 Helsinki
Finland

SRN: FI-MF-000006499

declare under our sole responsibility that the product

Intraoral Scanner **Planmeca Emerald S**
with UDI-DI (GMN) EU 6430035420205H

with intended use as an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation areas (including features such as implant scan locator fixtures, braces, brackets, etc.). In addition it can record the topographical characteristics of the oral anatomy (such as soft tissue, gingivae and palate). The three dimensionalmodel generated from the scan may be further used for study models, and for the design and manufacturing of dental restorations including implant supported prosthesis and full and partial frameworks, and can be used to design and manufacture physical models of the teeth.It may be used in conjunction with production of orthodontic appliances, retainer and accessories.
The Cariosity tip enables the possibility to diagnose caries by transilluminating the tooth / teeth and a 2D picture can be stored for documentation where both transilluminated image and color image from the same area are stored to the database.

to which this declaration relates is in conformity with following standards or other normative documents

IEC 60601-1 + A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6 +A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

Product is in compliance with Medical Device Regulation (EU) 2017/745. Product is in compliance with the essential requirements Annex I of the aforementioned Regulation. The device technical file is in compliance with Annex II and Annex III of the aforementioned Regulation.

Planmeca Emerald S is Class I device as classified according to rules set out in Rule 13, 6.5 of Annex VIII of the aforementioned regulation.

PLANMECA

Helsinki, 2022-09-06

Niina Vuorikallas
Director, Quality & Regulatory Affairs