PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland
SRN: FI-MF-000006499

declare under our sole responsibility that the product

Planmeca **Viso G5**
with BASIC UDI-DI (GMN) **6430035420145N**

with intended use as a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

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

IEC 60601-1 + A1:2012 + A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2 + A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-1-3 + A1:2013 + A2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment.
IEC 60601-1-6 + A1:2013 +A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 60601-2-63 +A1:2017 +A2:2021	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
IEC 62304 + A1:2015	Medical device software - Software life cycle processes.
IEC 62366-1 + A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices.

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. The product applies conformity assessment route as per Annex IX of aforementioned regulation.

Planmeca Viso G5 is Class IIb device as classified according to rule 10 as set out in Annex VIII of the aforementioned regulation.

The product is in compliance following the provisions of the essential requirements of Directive 2006/42/EC in applicable parts

EC certificate: FI23/00000059, issue 2
The Notified Body is SGS Fimko Ltd. no 0598.

The product is in compliance with Directive 2011/65/EU and Directive 2015/863.
The product is in compliance with Regulation (EC) No 1907/2006 in applicable parts.

Helsinki, 05.07.2024

Niina Vuorikallas
Director, Quality & Regulatory Affairs