PLANMECA

DECLARATION OF CONFORMITY

We

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

declare under our sole responsibility that the product

Intra-oral X-ray unit **Planmeca ProX**
with BASIC UDI-DI (GMN) 6430035420095V

with intended purpose as an extraoral X-ray source intended for 2D intraoral imaging. It is intended to be used together with intraoral receptors for dental radiographic examinations, diagnosis and follow up of diseases of the teeth, jaw and oral structures.

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 safety
IEC 60601-1-2 + A1:2020	Medical electrical equipment - Part 1: General requirements for safety, 2: Collateral standard: Electromagnetic compatibility. Requirements and tests
IEC 60601-1-3 + A1:2013	Medical electrical equipment – Part 1: General requirements for safety, 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-28:2017	Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies for medical diagnosis
IEC 60601-2-65 + A1:2017	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

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IEC 62304 + A1:2015	Medical device software - Software life cycle processes.
IEC 62366-1:2015+A1:2020	Medical devices –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 product applies conformity assessment route as per Annex IX of aforementioned regulation.

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

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

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

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, 03.07.2024

Niina Vuorikallas
Director, Quality & Regulatory Affairs