

DECLARATION OF CONFORMITY

We

**Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland**

declare under our sole responsibility that the product

Planmeca ProMax 3D

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 60601-1-3 + A1:2013	Medical electrical equipment - Part 1: General requirements for safety. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-2-63 + A1:2017	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 + A1:2014	Medical devices – Part 1: Application of usability engineering to medical devices.

following the provisions of **Council Directive 93/42/EEC** as set out in **Annex II**.
Planmeca ProMax 3D is Class IIb device.

EC certificate: FI15/07006

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2021-05-25



Niina Vuorikallas
Director, Quality & Regulatory Affairs

Letter for Compliance

We

**Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
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declare under our sole responsibility that the product KaVo ProXam 3D is substantially equal with Planmeca ProMax 3D from a technical point of view and differ only in optical appearance.

Therefore, the Declarations of Conformity for Planmeca ProMax 3D, dated 25.5.2021 following the provisions of **Council Directive 93/42/EEC** is also valid for the KaVo ProXam 3D.

Helsinki, 2023-03-23



Niina Vuorikallas
Director, Quality & Regulatory Affairs