PLANMECA

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

PLANMECA

Letter for Compliance

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

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