

## DECLARATION OF CONFORMITY

We

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

declare under our sole responsibility that the product

**Planmeca ProMax 3D Plus**

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

<b>IEC 60601-1 + A1:2012</b>	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
<b>IEC 60601-1-2:2014</b>	Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
<b>IEC 60601-1-6 + A1:2013</b>	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
<b>IEC 60601-1-3 + A1:2013</b>	Medical electrical equipment - Part 1: General requirements for safety. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
<b>IEC 60601-2-63 + A1:2017</b>	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
<b>IEC 62304 + A1:2015</b>	Medical device software - Software life cycle processes.
<b>IEC 62366 + A1:2014</b>	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 Plus is Class IIb device.

EC certificate: FI15/07006

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2021-05-21



Niina Vuorikallas  
Director, Quality & Regulatory Affairs