PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Intra-oral X-ray **Planmeca ProX**

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 60601-1-2:2014	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 60601-2-28:2010	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
IEC 62304 + A1:2015	Medical device software - Software life cycle processes.
IEC 62366 + A1:2014	Medical devices –Application of usability engineering to medical devices.

following the provisions of **Council Directive 93/42/EEC** as set out in **Annex II**.
Planmeca ProX 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