PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Planmeca **ProOne**

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 60601-2-63:2012	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
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 60601-1-6 + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 62304:2006	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 ProOne 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