PLANMECA

DECLARATION OF CONFORMITY

Digitally signed by Chicu Natalia
Date: 2021.09.15 17:57:31 EEST
Reason: MoldSign Signature
Location: Moldova

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	International standard on general safety for medical electrical equipment
IEC 60601-1-2	Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
IEC 60601-2-7	Medical electrical equipment part 2: Particular requirements for safety of highvoltage generators of diagnostic x-ray generators
IEC 60601-1-3	Medical electrical equipment - Part 1: General requirements for safety. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-2-28	Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-32	Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment

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

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2014-02-27

Olli Heikkinen
Quality Director