

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:

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|-----------------------|--|
| 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**.
Promax 3D is Class IIb device.

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2014-02-27



Olli Heikkinen
Quality Director