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

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|---|---|
| **IEC 60601-1 ed.2** | Medical electrical equipment - Part 1: General requirements for safety |
| **IEC 60601-1-1 ed.2** | Medical electrical equipment - Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems |
| **IEC 60601-1-2 ed.2** | Medical electrical equipment - Part 1: General requirements for safety, 2: Collateral standard: Electromagnetic compatibility. Requirements and tests |
| **IEC 60601-1-3 ed.1** | Medical electrical equipment – Part 1: General requirements for safety, 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment |
| **IEC 60601-1-4 ed.1** | Medical electrical equipment - Part 1: General requirements for safety, 4: Collateral standard: Programmable electrical medical systems |
| **IEC 60601-2-7 ed.2** | Medical electrical equipment – Part 2: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators |
| **IEC 60601-2-28 ed.1** | Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies for medical diagnosis |
| **IEC 60601-2-32 ed.1** | Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment |

following the provisions of **93/42/EEC Directive**.
Planmeca ProX is Class IIb device.

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2014-02-27

Olli Heikkinen
Quality Director