PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
FIN-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 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 VTT Expert Services Oy no. 0537.

Helsinki, 2013-03-13

Olli Heikkinen
Quality Director