

## DECLARATION OF CONFORMITY

We

**Planmeca Oy,  
Asentajankatu 6,  
FIN-00880 Helsinki  
Finland**

declare under our sole responsibility that the product

**Panoramic X-ray unit Planmeca Proline XC**

to which this declaration relates is in conformity with following standards or other normative documents

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

The Notified Body involved is VTT Automation no. 0537.

Helsinki, 2005-04-22



Olli Heikkinen  
Quality Director