

DECLARATION OF CONFORMITY

We

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

declare under our sole responsibility that the product

Dental Care Unit **Planmeca Sovereign Classic**

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 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2-60	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
IEC 62366	Medical devices - Application of usability engineering to medical devices
ISO 7494	International Standard for Dental Unit
ISO 6875	International standar for Electromedical Dental Patient Chair

following the provisions of **Council Directive 93/42/EEC** as set out in **Annex II**.
Planmeca Sovereign Classic is Class IIa device.

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2014-03-12



Olli Heikkinen
Quality Director