PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Romexis Software

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

IEC 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems

following the provisions of **93/42/EEC Directive** as set out in **Annex II**.
Romexis is Class IIb device.

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2014-02-27

Olli Heikkinen
Quality Director