PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Planmeca Romexis

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

IEC 62366 + A1:2014	Medical devices – Application of usability engineering to medical devices
IEC 62304 + A1:2015	Medical device software – Software life-cycle processes

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

EC certificate: FI15/07006
The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2020-09-15

Niina Vuorikallas
Director, Quality & Regulatory Affairs