PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Dental Unit **Planmeca Compact i**
sub-models: Planmeca Compact i3
Planmeca Compact i5
Planmeca Compact i Classic
Planmeca Compact i Touch

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

IEC 60601-1 +A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6 +A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2-60:2012	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
IEC 62304 + A1:2015	Medical device software – Software life-cycle processes
ISO 7494-1:2018	Dentistry – Dental units – Part 1: General requirements and test methods
ISO 7494-2:2015	Dentistry – Dental units – Part 2: Air, water, suction and wastewater systems

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

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

Helsinki, 2021-08-10

Niina Vuorikallas
Director, Quality & Regulatory Affairs