PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland
SRN: FI-MF-000006499

declare under our sole responsibility that the product

Dental Unit **Planmeca Compact i**
with BASIC UDI-DI (GMN) **6430035420075R**
sub-models: **Planmeca Compact i3**
Planmeca Compact i5
Planmeca Compact i Classic
Planmeca Compact i Touch

with intended use as a system intended for use in dental care medical operations.

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 + A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2-60:2019	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
IEC 62366-1:2015 +A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
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

Product is in compliance with Medical Device Regulation (EU) 2017/745. Product is in compliance with the essential requirements Annex I of the aforementioned Regulation. The product applies conformity assessment route as per Annex IX of aforementioned regulation.

Planmeca Compact i is Class IIa device as classified according to rule 9 as set out in Annex VIII of the aforementioned regulation.

EC certificate: FI23/00000059, issue 2
The Notified Body is SGS Fimko Ltd. no 0598.

The product is in compliance following the provisions of the essential requirements of Directive 2006/42/EC in applicable parts.

The product is in compliance with Directive 2011/65/EU and Directive 2015/863.
The product is in compliance with Regulation (EC) No 1907/2006 in applicable parts.

Helsinki, 25.06.2024

Niina Vuorikallas
Director, Quality & Regulatory Affairs