PLANMECA

DECLARATION OF CONFORMITY

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product

Planmeca **ProSensor HD**

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 62366 + A1:2014	Medical devices – Part 1: Application of usability engineering to medical devices.

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

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

Helsinki, 2021-05-25

Niina Vuorikallas
Director, Quality & Regulatory Affairs

PLANMECA

Letter for Compliance

We

Planmeca Oy,
Asentajankatu 6,
00880 Helsinki
Finland

declare under our sole responsibility that the product trademark KaVo ProXam iS is substantially equal with Planmeca ProSensor HD from a technical point of view and differ only in optical appearance.

Therefore, the Declarations of Conformity for Planmeca ProSensor HD, dated 25.5.2021 following the provisions of **Council Directive 93/42/EEC** is also valid for the trademark KaVo ProXam iS.

Helsinki, 2023-03-23

Niina Vuorikallas
Director, Quality & Regulatory Affairs