EC Certificate Full Quality Assurance System FI15/07006

The management system of

Planmeca Oy

Asentajankatu 6
00880 Helsinki
Finland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section IV)

For the following products

Dental units, dental chairs and accessories. Dental diagnostic X-ray equipment, diagnostic X-ray equipment, X-ray software and accessories

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 20 December 2019 until 13 November 2023
and remains valid subject to satisfactory surveillance audits.
Issue 7. Certified since 8 October 2010
This certification is based on decision: FI18/07015P2

Authorised by

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Tom Törn
Certification Director

SGS Fimko Ltd., Notified Body 0598
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Attachment 1 to SGS Fimko Ltd. EC certificate FI15/07006, Issue 7

Manufacturer	Planmeca Oy
Address	Asentajankatu 6, 00880 Helsinki, Finland
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) Dental units, dental chairs and accessories. Dental diagnostic X-ray equipment, diagnostic X-ray equipment, X-ray software and accessories.

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Dental unit	IIa	Planmeca Sovereign
Dental unit	IIa	Planmeca Sovereign Classic
Dental unit	IIa	Planmeca Compact i, comprised of sub-models - Planmeca Compact i5 (serial numbers UPCVNNNNNN, where N stand for any number) - Planmeca Compact i3 (serial numbers UPCLNNNNNN, where N stand for any number) - Planmeca Compact i Touch (serial numbers UTTGNNNNNN, where N stands for any number) - Planmeca Compact i Classic (serial numbers UCIGNNNNNN, where N stands for any number)
Dental unit accessories, Micromotors	IIa	Planmeca Type 801
Dental unit accessories, Micromotors	IIa	Planmeca Minendo
Dental unit accessories, Micromotors	IIa	Planmeca Minetto
Dental intra-oral x-ray system	IIa	Planmeca ProSensor
Dental intra-oral x-ray system	IIa	Planmeca ProSensor HD
Dental intra-oral x-ray unit	IIb	Planmeca ProX
X-ray unit	IIb	Planmeca ProMax 3D
X-ray unit	IIb	Planmeca ProMax 3D s
X-ray unit	IIb	Planmeca ProMax 3D Max
X-ray unit	IIb	Planmeca ProMax 3D Mid
X-ray unit	IIb	Planmeca ProMax 3D Plus
X-ray unit	IIb	Planmeca Viso G5
X-ray unit	IIb	Planmeca Viso G7
Panoramic dental X-ray unit	IIb	Planmeca ProMax
Panoramic dental X-ray unit	IIb	Planmeca ProOne
X-ray software	IIb	Planmeca Romexis
Disinfectant for dental instrument	IIa	Planmeca Planosil
Dental optical impression system	Im	Planmeca PlanScan
Dental optical impression system	Im	Planmeca Emerald

Planmeca Oy

Asentajankatu 6,
00880 Helsinki,
Finland

Notified Body Letter of Confirmation

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Fimko Ltd, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0598 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Planmeca Oy

Asentajankatu 6,
00880 Helsinki,
Finland

SRN Number: FI-MF-000006499

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Helsinki, 25 September 2023

Seppo Vahasalo
Notified Body Manager

SGS Fimko Ltd

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
X-ray unit, models: Planmeca ProMax, Planmeca ProMax 3D, Planmeca ProMax 3D Plus, Planmeca ProMax 3D Mid, Planmeca ProOne, Planmeca Viso G5, Planmeca Viso G7	IIb	N/A	FI15/07006 - Issue 9 NB0598
Dental intra-oral x-ray unit, models: Planmeca ProX	IIb	N/A	FI15/07006 - Issue 9 NB0598
Dental intra-oral x-ray systems, models: Planmeca Prosensor HD	IIa	N/A	FI15/07006 - Issue 9 NB0598
X-ray software, models: Planmeca Romexis	IIb	N/A	FI15/07006 - Issue 9 NB0598
Dental unit, models: Planmeca Compact i	IIa	N/A	FI15/07006 - Issue 9 NB0598

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			