

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 4)

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 10 May 2021 until 13 November 2023 and remains valid subject to satisfactory surveillance audits.

Issue 9. Certified since 8 October 2010

This certification is based on decision: FI21/07046P0

Authorised by

FINAS
Finnish Accreditation Service
\$1003 (FM ISOLIEC 17065)

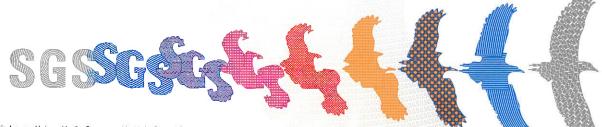


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Attachment 1 to SGS Fimko Ltd. EC certificate Fl15/07006, issue 9

Manufacturer	Planmeca Oy		
Address	Asentajankatu 6, 00880 Helsinki, Finland		
Activity and Medical	93/42/EEC Annex II (excluding Section 4)		
Device Product Category	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	Ula SUBSECTION OF SUBSECTION O	Planmeca Compact i, comprised of sub-models - Planmeca Compact i5 (serial numbers
Dental intra-oral x-ray system	lla	Planmeca ProSensor HD
Dental intra-oral x-ray unit	IIb	Planmeca ProX
X-ray unit	lib	Planmeca ProMax 3D
X-ray unit	llb	Planmeca ProMax 3D s
X-ray unit	llb	Planmeca ProMax 3D Mid
X-ray unit	llb	Planmeca ProMax 3D Plus
X-ray unit	llb	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	lla	Planmeca Planosil

