

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.

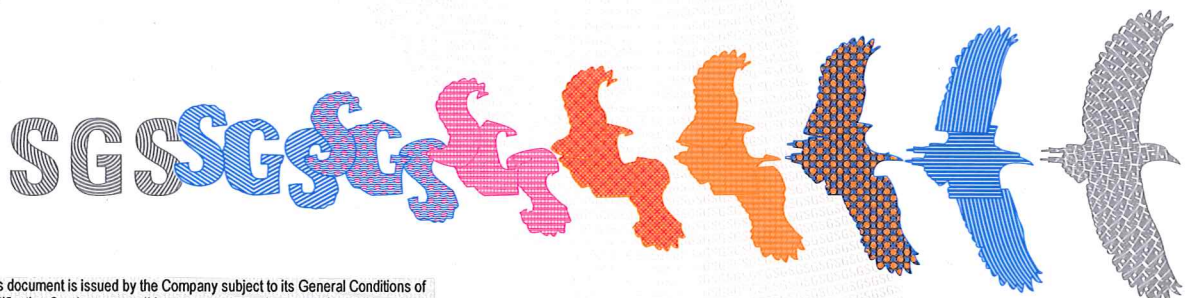
Issue 7. Certified since 8 October 2010

This certification is based on decision: FI18/07015P2

Authorised by

Tom Törn  
Certification Director

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## Attachment 1 to SGS Fimko Ltd. EC certificate FI15/07006, Issue 7

<b>Manufacturer</b>	Planmeca Oy
<b>Address</b>	Asentajankatu 6, 00880 Helsinki, Finland
<b>Activity and Medical Device Product Category</b>	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	Ila	Planmeca Sovereign
Dental unit	Ila	Planmeca Sovereign Classic
Dental unit	Ila	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	Ila	Planmeca Type 801
Dental unit accessories, Micromotors	Ila	Planmeca Minendo
Dental unit accessories, Micromotors	Ila	Planmeca Minetto
Dental intra-oral x-ray system	Ila	Planmeca ProSensor
Dental intra-oral x-ray system	Ila	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	Ila	Planmeca Planosil
Dental optical impression system	Im	Planmeca PlanScan
Dental optical impression system	Im	Planmeca Emerald