

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

Seppo Vahasalo  
Notified Body Manager

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## Attachment 1 to SGS Fimko Ltd. EC certificate FI15/07006, issue 9

<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 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 intra-oral x-ray system	Ila	Planmeca ProSensor HD
Dental intra-oral x-ray unit	Ilb	Planmeca ProX
X-ray unit	Ilb	Planmeca ProMax 3D
X-ray unit	Ilb	Planmeca ProMax 3D s
X-ray unit	Ilb	Planmeca ProMax 3D Mid
X-ray unit	Ilb	Planmeca ProMax 3D Plus
X-ray unit	Ilb	Planmeca Viso G5
X-ray unit	Ilb	Planmeca Viso G7
Panoramic dental X-ray unit	Ilb	Planmeca ProMax
Panoramic dental X-ray unit	Ilb	Planmeca ProOne
X-ray software	Ilb	Planmeca Romexis
Disinfectant for dental instrument	Ila	Planmeca Planosil

