



EC Certificate Full Quality Assurance System FI15/07006-1

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 9 October 2015 until 8 October 2020
and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 8 October 2018

Issue 1. Certified since 8 October 2010

This certification is based on decision: FI15/07006P0

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598



SGS Fimko Ltd

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Business ID 0978538-5

Member of the SGS Group (SGS SA)

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

Manufacturer	Planmeca Oy
Address	Asentajankatu 6, 00880 Helsinki, Finland
Activity and 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 product names and the corresponding product type/model markings with trademarks/marketing names covered by this certificate:

Product Name	Class	Model/type nr. and Trademark(s)
Dental unit	Ila	Planmeca Sovereign
Dental unit	Ila	Planmeca Sovereign Classic
Dental unit	Ila	Planmeca Compact i
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	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 Max
X-ray unit	Ilb	Planmeca ProMax 3D Mid
X-ray unit	Ilb	Planmeca ProMax 3D Plus
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
Dental optical impression system	Im	Planmeca PlanScan
Dental optical impression system	Im	Planmeca Emerald



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Date issued/revised: 2.10.2017, issue 3

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Anexa nr. 8 **IMPRIMANTĂ USCATĂ LASER PE PELICULĂ RADIOLOGICĂ,**
model DryPro 832 (Konica Minolta, Japonia)

Nr.	Denumirea bunurilor
8.	8. IMPRIMANTĂ USCATĂ LASER PE PELICULĂ RADIOLOGICĂ, DryPro 832 Imprimanta laser de tip uscat, cu calculator inclus pentru pelicula radiologică Imprimanta laser pentru pelicula radiologică, de tip „table-top” • Dispune de 2 tavite. • Tehnologie de imprimare de tip laser • Echipata cu doua sertare pentru utilizarea simultana a doua formate diferite de film • Dimensiuni filme acceptate: minim "8x10", "11x14", "14x17", "14x14", "10x12". • Capacitate procesare 90 filme/ora • Timp de imprimare: 50 sec • Capacitate tava filme: 125 filme per tavă • Interfață: Ethernet – conexiune externă la PC • Rezoluție printare: 320 dpi • Gradație de ieșire 12 biți • Compatibilitate DICOM • Corecție automată a densității • Condiții de operare: 15-30 grade Celsius • Nivelul de zgomot: mai puțin de 53dB la printare; mai puțin de 46dB in mod stand by; • Greutatea 117 kg. • Termen de Garantie 24 luni de la momentul dării în exploatare; • La solicitare obligatoriu se vor prezenta certificatele de calitate CE, ISO; Certificate de la producător despre pregătirea a min. doi ingineri care se vor ocupa cu montarea și adaptarea tehnicii. • Pregătirea (școlarizarea) specialiștilor Centrului Stomatologic Universitar.

