



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



The Ministry for Foreign Affairs of Finland certifies that

whose signature and seal appear under the foregoing certificate, is authorized to issue certificates of that nature.

Helsinki, No. Fee €

UUDENMAAN MAISTRAATTI
LOCAL REGISTER OFFICE OF UUSIMAA
ALBERTINKATU 25
00180 HELSINKI FINLAND
TEL. +358 2 955 36222

I hereby certify that this is a correct and true copy of the original document which I have seen.
Helsinki

05.05.2017

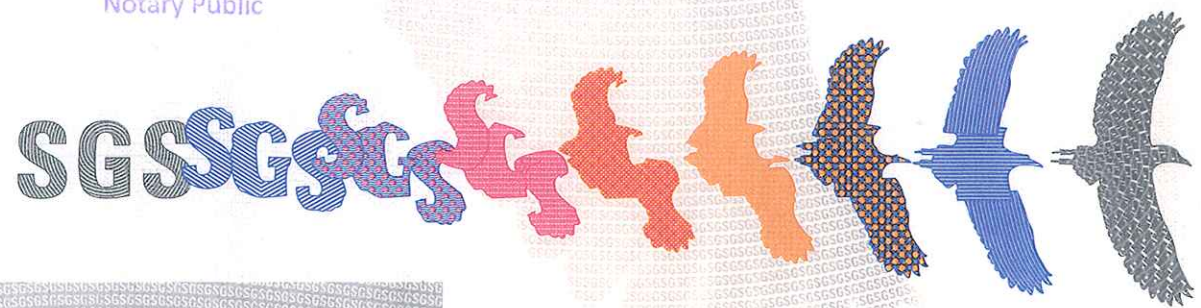
Paula Ojanemi
PAULA OJANEMI
Notary Public



Authorised by

Tom Törn

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





ĐẠI SỨ QUÁN NƯỚC CHXHCNVN TẠI PHẦN LAN
EMBASSY OF THE S.R OF VIETNAM IN FINLAND
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

5 Quốc gia: **VIỆT NAM**
Country:

Giấy tờ, tài liệu này
This public document

6 Do Ông (Bà) : **Paivi Syrjasuo** ký
Has been signed by

7 Với chức danh: **Thư ký**
Acting in the capacity of

8 Và con dấu của **BỘ NGOẠI GIAO PHẦN LAN**
Bears the seal/stamp of

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại: Helsinki 6. Ngày **22/5/17**
in: the
Cơ quan cấp : **ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI PHẦN LAN**

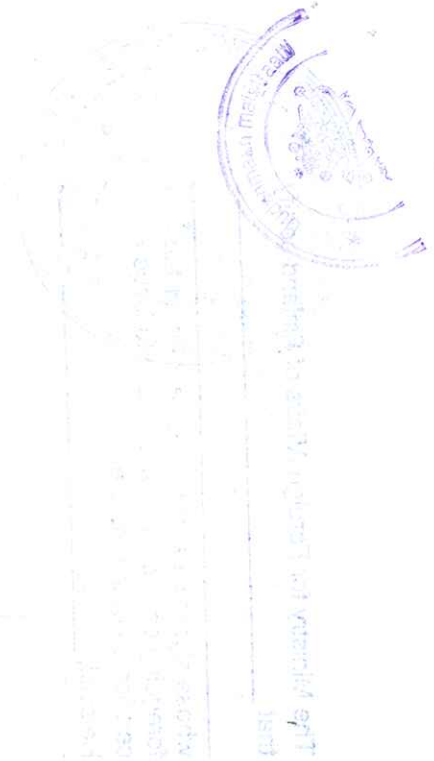
by:
7 Số : 312
Number

TL. Đại sứ/ For the Ambassador
Bí thư thứ nhất/First Secretary

TRẦN QUANG XUÂN UYÊN



UDENMAAN MAISTRA
LOCAL REGISTER OFFICE OF
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00180 HELSINKI FINL
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Attachment 1 to SGS Fimko Ltd. EC certificate FI15/07006-1

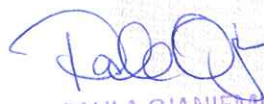
Manufacturer	Planmeca Oy
Address	Asentajankatu 6, 00880 Helsinki, Finland
Activity and Product Category	93/42/EEC Annex II (excluding Section 4) Dental units, dental chairs and accessories. Dental diagnostic X-ray equipment, diagnostic X-ray equipment, X-ray software and accessories.

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 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
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

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Helsinki 05.05.2017


PAULA OJANIEMI
Notary Public

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SGS Fimko Ltd., Notified Body 0598

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Date issued/revised: 9.10.2015