EC CERTIFICATE

Certificate No 1055/MDD

Annex

Dental intraoral systems
Type ref. RX AC; RX DC; RX DC Plus; RX DC eXTend; RX DC/I; RX DC Plus/I.
Trade mark myray

Panoramic and cephalometric X-ray systems
Series: hyperion Type ref. hyperion MRT; hyperion.
Trade mark myray

Panoramic, cephalometric and tomographic X-ray system
Type ref. hyperion X9; hyperion X9 pro; hyperion X5.
Trade mark myray

Digital radiography systems
Type ref. ZEN-X; ZEN-Xi; X-VS; X-VSi.
Trade mark myray

Digitals videoradiographic sensors
Type ref. WDS X POD.
Trade mark myray

Devices for recording X-ray imaging for intra oral images
Type ref. hy-scan; X-PSP.
Trade mark myray

Date: 2007-07-23
Updated: 2019-09-03
Substitution Date: 2019-04-19
Expiry Date: 2024-05-26

IMQ

Digitally signed by Benderschi Tamara
Date: 2019.10.25 14:37:15 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA, mun. CHIȘINĂU, s. BUBUIECI
IDNO 1002600029967
S.R.L. «PRODENT-COM»
Nr. 2
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1055/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CEFLA S.C.

40026 IMOLA (BO) - VIA SELICE PROVINCIALE 23/A (ITA) - Italy

manages in the factory of:

40026 IMOLA (BO) - VIA BICOCCA,14/C (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Dental intraoral systems

Panoramic and cephalometric X-ray systems

Panoramic, cephalometric and tomographic X-ray system

Digital radiography systems

Digitals videoradiographic sensors

Devices for recording X-ray imaging for intra oral images

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0019521-01; DM18-0028863-01; DM18-0033512-01; DM19-0037464-01; DM19-0039391-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2007-07-23
Updated:	2019-09-03
Substitution Date:	2019-04-19
Expiry Date:	2024-05-26

DocuSign

IMQ

REPUBLICA MOLDOVA, mun. CHISINAU, s. BUBUIECI IDNO 1002600029967 S.R.L. «PRODENT-COM» Nr. 2 SOCIETATEA CU RASPUNDERE LIMITATA

CERTIFICATO CE

Certificato n. 1055/MDD

Allegato

Sistemi radiografici endorali
Modd. RX AC; RX DC; RX DC Plus; RX DC eXTend; RX DC/I; RX DC Plus/I.
Marca myray

Sistemi radiologici panoramici e cefalometrici
Serie: hyperion Modd. hyperion MRT; hyperion.
Marca myray

Sistemi radiologici panoramici, cefalometrici e tomografici
Modd. hyperion X9; hyperion X9 pro; hyperion X5.
Marca myray

Sistemi per radiografie digitali
Modd. ZEN-X; ZEN-Xi; X-VS; X-VSi.
Marca myray

Sensori videoradiografici digitali
Mod. WDS X POD.
Marca myray

Dispositivi per la registrazione di immagini per raggi x ad uso intraorale dentale
Modd. hy-scan; X-PSP.
Marca myray

Emesso il:	2007-07-23
Data aggiornamento:	2019-09-03
Sostituisce:	2019-04-19
Data scadenza:	2024-05-26

DocuSign

IMQ

REPUBLICA MOLDOVA, mun. CHIȘINĂU, s. BUBUIECI
IDNO 1002600029967
S.R.L. «PRODENT-COM» Nr. 2
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

CERTIFICATO CE

Certificato n. 1055/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CEFLA S.C.

40026 IMOLA (BO) - VIA SELICE PROVINCIALE 23/A (ITA) - Italy

mantiene nello stabilimento di:

40026 IMOLA (BO) - VIA BICOCCA,14/C (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Sistemi radiografici endorali

Sistemi radiologici panoramici e cefalometrici

Sistemi radiologici panoramici, cefalometrici e tomografici

Sistemi per radiografie digitali

Sensori videoradiografici digitali

Dispositivi per la registrazione di immagini per raggi x ad uso intraorale dentale

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM17-0019521-01; DM18-0028863-01; DM18-0033512-01; DM19-0037464-01; DM19-0039391-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2007-07-23
Data aggiornamento:	2019-09-03
Sostituisce:	2019-04-19
Data scadenza:	2024-05-26

DocuSign

IMQ

REPUBLICA MOLDOVA, mun. CHIŞINĂU, s. BUBUIECI IDNO 1002600029967 S.R.L. «PRODENT-COM» Nr. 2 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Ref. Certificate No.
IT-15565/B1/M1

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Panoramic and tomographic X-Ray system
Name and address of the Applicant Nom et adresse du demandeur	CEFLA S.C. VIA SELICE PROVINCIALE 23/A 40026 IMOLA BO Italy
Name and address of the manufacturer Nom et adresse du fabricant	CEFLA S.C. VIA BICOCCA 14/C 40026 IMOLA BO Italy
Name and address of the factory Nom et adresse de l'usine	CEFLA S.C. VIA BICOCCA 14/C 40026 IMOLA BO Italy
Rating and principal characteristics Valeurs nominales et caractéristiques principales	115-240 Vac; 20-12 A; 50/60 Hz
Trademark (if any) Marque de fabrique (si elle existe)	myray
Type of manufacturer's Testing Laboratories used Type de programme de laboratoire d'essais constructeur	TMP
Model / Type Ref. Réf. de type	hyperion X5
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiquées sur la 2ème page)	This CBTC is a modification to CBTC No. IT-15565/B1 dated 2015-05-05 and they must be read in conjunction. Modification introduced: Change of manufacturer identification from CEFLA S.C - CEFLA DENTAL GROUP to CEFLA S.C.
A sample of product was tested and found to be in conformity with IEC Un échantillon de ce produit a été essayé et été considéré conforme à la CEI	60601-1-3(ed.2) 60601-1-6(ed.3) 60601-1(ed.3) 60601-2-63(ed.1) 62304(ed.1) 62366(ed.1)
National differences / Comments Les différences nationales / Commentaires	CA, US
As shown in the test report Ref. No. which forms part of this certificate Comme indiqué dans le rapport d'essais numéro de référence qui constitue partie de ce certificat	10SO00141-M1

This CB Test Certificate is issued by the National Certification Body:

IMQ S.p.A.
Via Quintiliano 43 I-20138 Milano, Italy

Ce Certificat d'essai OC est établi par l'Organisme National de Certification

IMQ

Date: 2015-10-09

Signature: Filippo Brivio

cosign

Ref. Certif. No.
IT-20094/B1

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product	Dental X-Ray unit
Name and address of the applicant	CEFLA S.C. VIA SELICE PROVINCIALE 23/A 40026 IMOLA BO Italy
Name and address of the manufacturer	CEFLA S.C. VIA SELICE PROVINCIALE 23/A 40026 IMOLA BO Italy
Name and address of the factory Note: *When more than one factory, please report on page 2*	☐ Additional information on page 2 CEFLA S.C. VIA BICOCCA 14/C 40026 IMOLA BO Italy
Ratings and principal characteristics	230-240 V, 50/60 Hz, 6 A 115-120 V, 50/60 Hz, 10 A
Trademark (if any)	myray
Customer's Testing Facility (CTF) Stage used	
Model / Type Ref.	RX DC, RX DC/I, RX DC Plus, RX DC Plus/I, RX DC eXTend
Additional information (if necessary may also be reported on page 2)	☐ Additional information on page 2 -
A sample of the product was tested and found to be in conformity with	IEC 60601-1-2:2014
As shown in the Test Report Ref. No. which forms part of this Certificate	DM18-0032252-01

This CB Test Certificate is issued by the National Certification Body

IMQ S.p.A.
Via Quintiliano 43, IT-I-20138 Milano, Italy

Date: 2019-05-10

Signature: Mauro Casari cosign