

# 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 factories of:

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

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

**Dental intraoral systems**

**Volumetric Tomograph**

**Panoramic and cephalometric X-ray systems**

**Panoramic, cephalometric and tomographic X-ray system**

**Panoramic and tomographic X-ray systems**

**Digital radiography systems**

**Digitals videoradiographic sensors**

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.

Reference to IMQ files Nos: 10AH00051; 10AH00070; 10AH00164; 10SI00031; 10SI00032;  
10SI00033; 10AI00111; 10AI00213; 10AK00062; 10AK00036;  
10EK00072; 10AK00252; 10EM00037; 10AO00056; 10AO00059;  
DM15A0493491-01.

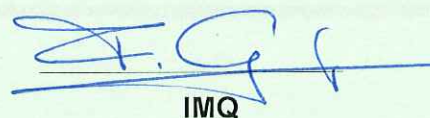
This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.

Notified Body notified to European Commission under number: 0051.

Date: 2007-07-23

Updated: 2015-09-08

Substitution Date: 2014-04-29



IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".  
In any case, it does not remain valid after 2017-07-15 (article 11, clause 11 of the Directive).

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

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## Annex

### Dental intraoral systems

Type ref. RX AC; RX DC (versions: RX DC, RX DC Plus, RX DC eXTend);  
RX DC / I (versions: RX DC/I, RX DC Plus/I); RX DC VET; RX DC VET XT.  
Trade mark myray

### Volumetric Tomograph

Type ref. SkyView.  
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  
Trade mark myray

### Panoramic and tomographic X-ray systems

Type ref. hyperion X5  
Trade mark myray

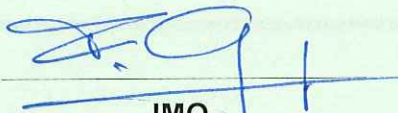
### Digital radiography systems

Type ref. ZEN-X; ZEN-Xi  
Trade mark myray

### Digitals videoradiographic sensors

Type ref. WDS; WDS X POD  
Trade mark myray

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