



# EC CERTIFICATE

Certificate No 1498/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 units**

**Digital radiography systems**

**Dental intraoral systems**

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

**Panoramic and cephalometric X-ray systems**

**Dental X-Ray systems, tubehead type for dental use**

**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:

10AM00004; 10AM00008; 10AO00061; 10AO00234; DM15A0493491-01; DM16-0002159; DM16-0010516-01; DM15A0578476-01; DM17-0010470; DM16-0010503-01; DM17-0016545-01; DM17-0019521-01; DM17-0020268-01; DM18-0033512-01; DM19-0037464-01; DM19-0038855-01; DM19-0039387-01; DM19-0039391-01; DM19-0046115-01; DM20-0049316-01; DM20-0048617-01; DM20-0056955-01.

**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: 2012-01-24  
Updated: 2021-02-03  
Substitution Date: 2020-05-13  
Expiry Date: 2024-05-26

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### Annex

#### Dental units

Type ref. PUMA ELI; PUMA ELI A; PUMA ELI CART; PUMA ELI CP; PUMA ELI ORTHO; PUMA ELI CART ISO; SKEMA 5 (REF 71C0); SKEMA 5 CP (REF 71C1); SKEMA 6 (REF 71C2); SKEMA 6 CP (REF 71C3); SKEMA 6 CART (REF 71C4); SKEMA 8 RS (REF 71C5); SKEMA 8 CP (REF 71C6); SKEMA 8 RS (REF 71C7); SKEMA 8 CP (REF 71C8); SKEMA 8; SKEMA 8 RS; SKEMA 8 CP; SKEMA 5; SKEMA 5 CP; SKEMA 5 ORTHO; SKEMA 6; SKEMA 6 CP; SKEMA 6 CART; PUMA ELI R (REF 71CA); PUMA ELI R CP (REF 71CB); PUMA ELI R CART (REF 71CC); PUMA ELI R CART ISO (REF 71CD); PUMA ELI R ORTHO (REF 71CE); PUMA ELI A R (REF 71CK); PUMA ELI A R CP (REF 71CL); PUMA ELI R; PUMA ELI R CP; PUMA ELI R CART; PUMA ELI R CART ISO; PUMA ELI R ORTHO; PUMA ELI A R; PUMA ELI A R CP; PUMA ELI A R CART; PUMA ELI A R M; PUMA ELI A R M CP; PUMA ELI A R M CART; PUMA ELI A R ORTHO; DAMA AMBIDX; SURGICAL SINGLE CART.  
Trade mark CASTELLINI

#### Digital radiography systems

Type ref. X-VS; X-VISUS; X-VSi; ZEN-X; ZEN-Xi.  
Trade mark CASTELLINI

#### Dental intraoral systems

Type ref. RX DC; RX DC Plus; RX DC eXTend; RX DC/I; RX DC Plus/I; X-SAFE.  
Trade mark CASTELLINI

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

Type ref. X-RADIUS TRIO; X-RADiUS TRiO PLUS; X-RADiUS COMPACT.  
Trade mark CASTELLINI

#### Panoramic and cephalometric X-ray systems

Type ref. X PAN 85.  
Trade mark CASTELLINI

#### Dental X-Ray systems, tubehead type for dental use

Type ref. X-SAFE 70.  
Trade mark CASTELLINI

#### Devices for recording X-ray imaging for intra oral images

Type ref. X-PSP.  
Trade mark CASTELLINI

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