

A17 + fethys



# EC CERTIFICATE

Certificate No 1716/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:

**Steam sterilizing units**

**Ultrasonic washer-disinfector**

**Dental units**

**Devices for cleaning and disinfection of dental instruments**

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:

10AO00167; 10AO00168; 10AO00169; 10AO00170; DM15A0493491-01; DM16-0000518; DM16A0612860-01; DM17-0009943-01; DM17-0016699-01; DM17-0019234-01; DM19-0037919-01; DM19-0039387-01; DM19-0039391-01; DM19-0040388-01; DM19-0045773-01; DM20-0048621-01; DM20-0055906-01; DM20-0057746-01.

**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.**

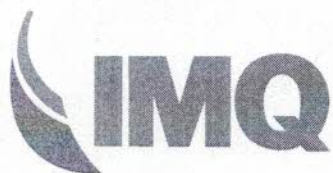


**TỔNG GIÁM ĐỐC**  
*Nguyễn Đức Chuẩn*



Date: 2014-10-09  
Updated: 2021-04-19  
Substitution Date: 2020-12-04  
Expiry Date: 2024-05-26

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### Annex

#### Steam sterilizing units

Type ref. S Classic-17; S Classic-22; S Classic-28; B Classic-17; B Classic-22; B Classic-28; B Futura-17; B Futura-22; B Futura-28; B Now-17; B Now-22; B Now-28; Supreme-17; Supreme-22; Supreme-28.

Trade mark MOCOM

Type ref. A-17S; A-22S; A-28S; A-17; A-22; A-28; A-17 PLUS; A-22 PLUS; A-28 PLUS; A-17T; A-22T; A-28T; A-17 PLATINUM; A-22 PLATINUM; A-28 PLATINUM.

Trade mark ANTHOS

Type ref. SW-17S; SW-22S; SW-28S; SW-17; SW-22; SW-28; SW-17 PLUS; SW-22 PLUS; SW-28 PLUS; SW-17T; SW-22T; SW-28T; SW-17 PLATINUM; SW-22 PLATINUM; SW-28 PLATINUM.

Trade mark STERN WEBER

Type ref. C-17S; C-22S; C-28S; C-17; C-22; C-28; C-17 PLUS; C-22 PLUS; C-28 PLUS; C-17T; C-22T; C-28T; C-17 PLATINUM; C-22 PLATINUM; C-28 PLATINUM.

Trade mark CASTELLINI

Type ref. Millennium B; Millennium B2; Neutra B, Neutra B2.

Trade mark MOCOM

Type ref. Evolution 6.0; Evolution 7.5; Evolution 9.0.

Type ref. Bravo G4 17; Bravo G4 22; Bravo G4 28.

#### Ultrasonic washer-disinfector

Type ref. Tethys H10; DeltaWash 10.

#### Dental units

Type ref. M10; M10 CONTINENTAL; M10 INTERNATIONAL.

Trade mark MOCOM

#### Devices for cleaning and disinfection of dental instruments

Type ref. Thalya Plus



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