CERTIFICATO CE

Certificato n. 1716/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:

Autoclavi di sterilizzazione a vapore d'acqua

Termodisinfettore ad ultrasuoni

Complessi odontoiatrici

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:

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.

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:	2014-10-09
Data aggiornamento:	2019-09-03
Sostituisce:	2019-05-22
Data scadenza:	2024-05-26

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IMQ

CERTIFICATO CE

Certificato n. 1716/MDD

Allegato

Autoclavi di sterilizzazione a vapore d'acqua

Modd. 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.
Marca MOCOM

Modd. 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.
Marca ANTHOS

Modd. 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.
Marca STERN WEBER

Modd. 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.
Marca CASTELLINI

Modd. Millennium B; Millennium B2; Neutra B, Neutra B2.
Marca MOCOM

Termodisinfettore ad ultrasuoni

Modd. Tethys H10; DeltaWash 10.

Complessi odontoiatrici

Modd. M10; M10 CONTINENTAL; M10 INTERNATIONAL.
Marca MOCOM

Emesso il:	2014-10-09
Data aggiornamento:	2019-09-03
Sostituisce:	2019-05-22
Data scadenza:	2024-05-26

DocuSign

IMQ

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

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.

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:	2014-10-09
Updated:	2019-09-03
Substitution Date:	2019-05-22
Expiry Date:	2024-05-26

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EC CERTIFICATE

Certificate No 1716/MDD

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

Ultrasonic washer-disinfector

Type ref. Tethys H10; DeltaWash 10.

Dental units

Type ref. M10; M10 CONTINENTAL; M10 INTERNATIONAL.
Trade mark MOCOM

Date:	2014-10-09
Updated:	2019-09-03
Substitution Date:	2019-05-22
Expiry Date:	2024-05-26

DocuSign

IMQ

/Vertimas iš anglų kalbos/

Ver. 4606/0

/logotipas: IMQ/

EB SERTIFIKATAS

Sertifikato Nr. 1716/MDD

Pilnos kokybės užtikrinimo sistemos aprobavimo sertifikatas

Remiantis mūsų patikrinimu, atliktu pagal Direktyvos 93/42/EEB II Priedą, išskyrus 4 skyrių, ir jos pakeitimus, mes liudijame, kad

CEFLA S.C.
40026 IMOLA (BO) – VIA SELICE PROVINCIALE 23/A (ITA) - Italija

gamykloje:

40026 IMOLA (BO) – VIA BICOCCA 14/C (ITA) – Italija

Pilnos kokybės užtikrinimo sistema, garantuoja šių gaminių atitiktį:

Gariniai sterilizatoriai
Plovimo ir dezinfekavimo įrenginiai
Odontologiniai įrenginiai
Serijos ir modeliai nurodyti Priede

anksčiau minėtos Direktyvos esminiams reikalavimams (nuo projektavimo iki galutinės patikros ir testavimo) ir jiems yra taikoma II Priedo 5 skyriuje numatyta priežiūra. III klasės prietaisams šis sertifikatas galioja tik kartu su taikomu EB Dizaino Įvertinimo sertifikatu pagal II Priedo 4 skyrių.

Nuoroda į IMQ bylas Nr.:
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; DM0040388-01.

Šį aprobavimo sertifikatą išdavė Direktyvos 93/42/EEB su jos pakeitimais notifikavimo įstaiga „IMQ S.p.A.“. Notifikavimo įstaiga registruota Europos Komisijoje numeriu: 0051.

Tvirtinu: 2021 05 18

Data:	2014-10-09
Atnaujinta:	2019-09-03
Pakeitimo data:	2019-05-22
Galiojimo data:	2024-05-26

/parašas/
IMQ

Direktorius
Andrius Vyčas

Šiam aprobavimo sertifikatui yra taikomos nuostatos, nurodytos „Medicinos prietaisų EB sertifikavimo taisyklėse pagal Direktyvą 93/42/EEB“.

„IMQ S.p.A.“. | Via Quintiliano 43 | I-20138 Milanas
www.imq.it

Vertimas iš italų kalbos teksto, kuriuo yra vadovaujamasi kilus abejonėms.

Ver. 4606/0

/logotipas: IMQ/

EB SERTIFIKATAS

Sertifikato Nr. 1716/MDD

Priedas

Gariniai sterilizatoriai
Modeliai: 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 Fututa-28; B Now-17; B Now-22; B Now-28; Supreme-17; Supreme-22; Supreme-28.
Prekinis ženklas „MOCOM“

Modeliai: 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.
Prekinis ženklas „ANTHOS“

Modeliai: 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.
Prekinis ženklas „STERN WEBER“

Modeliai: 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.
Prekinis ženklas „CASTELLINI“

Modeliai: Millenium B; Millenium B2; Neutra B; Neutra B2.
Prekinis ženklas „MOCOM“

Plovimo ir dezinfekavimo įrenginiai
Modeliai: Tethys H10; DentaWash 10.

Odontologiniai įrenginiai
Modeliai: M10; M10 CONTINENTAL; M10 INTERNATIONAL.
Prekinis ženklas „MOCOM“

Išrašytas: 2021 05 18

Data: 2014-10-09
Atnaujinta: 2019-09-03
Pakeitimo data: 2019-05-22
Galiojimo data: 2024-05-26

Direktorius
Andrius Vyčas

/parašas/

IMQ

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