EU DECLARATION OF CONFORMITY

Name of Manufacturer:	CEFLA s.c. Via Selice Provinciale, 23/A 40026 Imola (BO) Italy	**Plant:**	CEFLA s.c. Via Bicocca, 14/C 40026 Imola (BO) Italy
Single Registration Number (SRN):	IT-MF-000009228		
EU Certificate: ***(Reg. EU 2017/745)***	013/MDR	**Risk Class:** ***(Reg. EU 2017/745)***	IIb
Product Category:	Steam sterilizing units for medical purpose		
Trade Mark:	1-MOCOM 2-ANTHOS 3-CASTELLINI 4-STERN WEBER	**Model:**	1- S Classic-22, S Classic-28, B Classic-22, B Classic-28, B Futura-22, B Futura-28, B Now-22, B Now-28, Supreme-22, Supreme-28 2- A-22S, A-28S, A-22, A-28, A-22 PLUS, A-28 PLUS, A-22T, A-28T, A-22 PLATINUM, A-28 PLATINUM 3- C-22S, C-28S, C-22, C-28, C-22 PLUS, C-28 PLUS, C-22T, C-28T, C-22 PLATINUM, C-28 PLATINUM 4- SW-22S, SW-28S, SW-22, SW-28, SW-22 PLUS, SW-28 PLUS, SW-22T, SW-28T, SW-22 PLATINUM, SW-28 PLATINUM
Serial Number:		**Basic UDI-DI:**	803383793STAUTOCLB001TN

[EN] WE DECLARE, ON OUR SOLE RESPONSIBILITY, THAT THE PRODUCTS REFERRED TO HEREIN ARE IN COMPLIANCE WITH: to the general safety and performance requirements (Annex I) set out in Regulation (EU) 2017/745 on Medical Devices (MDR); to Directive 2011/65/EU of the European Parliament and of the Council of June 8, 2011 (RoHS 2), to Delegated Directive (EU) 2015/863 of the Commission of March 31, 2015, and subsequent amendments; to Directive 2014/53/EU (RED); to Directive 2014/68/EU (PED).

The above mentioned product entirely conforms to the standards:	EN 13060:2014 + A1:2018; IEC 61010-1:2010 + A1: 2016; EN IEC 61010-2-040:2021 (IEC 61010-2-040: 2020), EN IEC 61326-1:2021 (IEC 61326-1:2020); EN 62304:2006 + A1:2015 (IEC 62304:2006+A1:2015); EN 62366-1:2015 + A1:2020 (IEC 62366-1:2015 + A1:2020); EN 13445-3:2021; EN 4126-7:2016.

Conformity assessment procedure:	based on Regulation (EU) 2017/745 - Annex IX, Chapters I and III.
Notified body:	IMQ S.p.A. (0051) – Via Quintiliano, 43 – I-20138 Milan
Manufacturer's quality system:	ISO 9001:2015 (CERT. IMQ NO. 9120.CEFL) ISO 13485:2016 (CERT. IMQ NO. 9124.CEF3)

Intended purpose:	Small steam sterilizers intended for sterilization of invasive and non-invasive medical devices as reusable surgical instruments and materials

Additional information:	Directive 2014/68/EU (PED), Category II (Mod. A2, Annex III), CE Certificate A2 2021 FI PP 186 / 1 Notified Body: RINA Services S.p.A. (0474), Via Corsica, 12 – 16128 Genoa.

ITEM	PS (Bar)	TS (°C)	PED Category / PED MODULE	Manufacturer / SN
Vessel	+2.4	0/+140	II / -	CEFLA SC
Safety valve	+2.4	-20/+200	IV / H1	NGI SN Vedi Modulo DHR
Piping	10	-60/+180	Art 4.3 / -	ATAG SpA
Pressure switch	-0.9/+2.4	0/+125	Art 1.2 f iii / -	MA-TER
Electric boiler (steam generator)	+2.4	0/+270	Art. 4.3 / -	IRCA SpA

Imola, 2025/04/28

Paolo Bussolari
Cefla s.c. Managing Director
Business Unit Medical Equipment