



EU DECLARATION OF CONFORMITY

Manufacturer's Name:	CEFLA s.c. Via Selice Provinciale, 23/A 40026 Imola (BO) Italy	Factory:	CEFLA s.c. Via Bicocca, 14/C 40026 Imola (BO) Italy
Single Registration Number (SRN):	IT-MF-000009228		
CE Certificate: (Reg. 2017/745)	013/MDR	Risk class: (Reg. 2017/745)	IIb
Product Category:	Devices for washing and disinfecting dental instruments		
Brand:	-	Model:	Thalya Plus
Serial Number:	-	UDI-DI Basic:	803383793STDISDENB001GT

[EN] WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE PRODUCTS TO WHICH THIS DECLARATION REFERS ARE IN COMPLIANCE WITH: the general safety and performance requirements (Annex I) set out in the Medical Device Regulation (EU) 2017/745 (MDR); Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (Rohs 2); Commission Delegated Directive (EU) 2015/863 of 31 March 2015; Directive 2014/53/EU (RED).

The above-mentioned product is fully compliant with the following standards:	EN 61010-1:2010 + A1:2019 (IEC 61010-1:2010 + A1:2016); EN IEC 61010-2-040:2021 (IEC 61010-2-040:2020); EN 61326-1:2013 (IEC 61326-1:2012); EN 62304:2006 + A1:2015 (IEC 62304:2006 + A1:2015); EN 62366-1:2015 + A1:2020 (IEC 62366-1:2015 + A1:2020); EN ISO 14971:2019, EN ISO 14971:2019/A11:2021 (ISO 14971:2019); EN ISO 15223-1:2021 (ISO 15223-1:2021); EN ISO 20417:2021 (ISO 20417:2021).
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Conformity Assessment Procedure:	based on Reg. (EU) 2017/745 - Annex IX, Chapters I and III
Notified Body:	IMQ S.p.A. (0051) – Via Quintiliano, 43 – I-20138 Milano
Manufacturer's Quality System:	ISO 9001:2015 (CERT. IMQ NO. 9120.CEFL) ISO 13485:2016 (IMQ CERT NO. 9124.CEF3)

Intended use:	Device intended exclusively for internal lubrication and cleaning and disinfection of reusable dental instruments.
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Additional Information:	-
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Imola, 2023/11/08

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