



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)	-	Risk Class: (Reg. EU 2017/745)	I
Product Category:	Devices for lubrication of dental instruments		
Trade Mark:	-	Model:	Thalya
Serial Number:	-	Basic UDI-DI:	803383793STLUBDEN1001K4

WE DECLARE, ON OUR SOLE RESPONSIBILITY, THAT THE PRODUCTS REFERRED TO HEREIN ARE IN COMPLIANCE WITH:

- the general safety and performance requirements (Annex I) of Regulation (EU) 2017/745 on Medical Devices (MDR).
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2), with Commission Delegated Directive (EU) 2015/863 of 31 March 2015 and subsequent amendments.

The above mentioned product entirely conforms to the 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 (IEC 62366-1:2015)

Conformity assessment procedure: based on Reg. (EU) 2017/745 - Annex IV

Notified body: -

Manufacturer's quality system: ISO 9001:2015 (cert. IMQ no. 9120.CEFL)
ISO 13485:2016 (cert. IMQ no. 9124.CEF3)

Additional information: -

Imola, 2021/07/16

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