



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)	IIa				
Product Category:	Sensors for digital X-rays						
Brand/Model:	<table border="1"><thead><tr><th>Brand</th><th>Model</th></tr></thead><tbody><tr><td>-no brand-</td><td>X-VS, X-VS E, X-VSi</td></tr></tbody></table>			Brand	Model	-no brand-	X-VS, X-VS E, X-VSi
Brand	Model						
-no brand-	X-VS, X-VS E, X-VSi						
Serial Number:	-	UDI-DI Basic:	803383793IMXRAYINA001QX				

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, as amended.

The above-mentioned product is fully compliant with the following standards:

EN 60601-1:2006 + A1:2013 (IEC 60601-1:2005 + A1:2012); EN 60601-1-2:2015 (IEC 60601-1-2:2014); EN 60601-1-6:2010 + A1:2015 (IEC 60601-1-6:2010 + A1:2013); EN 62304:2006 + A1:2015 (IEC 62304:2006 + A1:2015); EN 62366-1:2015 + A1:2020 (IEC 62366-1:2015 + A1:2020)

Conformity Assessment Procedure: based on Reg. (EU) 2017/745 - Annex IX, Chapter I, III

Notified Body: IMQ S.p.A. (0051) – Via Quintiliano, 43 – I-20138 Milano (Reg. 2017/745)

Manufacturer's Quality System: ISO 9001:2015 (IMQ CERT. No. 9120.CEFL)
ISO 13485:2016 (IMQ CERT. N° 9124.CEF3)

Intended use: Intraoral digital sensors intended for the acquisition of intraoral digital images when exposed to X-rays, for diagnostic radiographic examination of human dentition (teeth, jaw and oral structures).

Additional Information: -

Imola, 2023/11/17

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