

EC Declaration of Conformity

Manufacturer's Name **FONA S.r.l.**
Legal site's address Via V. Hugo 4 – 20123 Milano (MI), Italy
Manufacturing site's address Via Galileo Galilei 11 - 20057 Assago (MI), Italy
Ref. Number *Product*

97 586 62320, 97 586 62620, 97 586 62820, **FONA XDG**
 97 586 62120, 97 586 67820, 97 546 62320, Dental X-Ray Systems
 97 546 62620, 97 546 62820, 97 546 62120,
 97 546 67830

made by a combination of the following articles

<i>Type Number</i>	<i>Article</i>
81 100 00900	Wall Adaptor
93 190 17100, 93 190 17200, 93 190 17300, 93 190 17400	Support Arm
81 100 12200	Scissor Arm
93 256 01300, 93 256 01700, 93 256 01800	X-ray Head 70 kVp, 3.5 mA
91 300 00020	6 cm Circular Field BLD
91 300 00040	3x4 cm X-ray Field BLD
93 356 60100, 93 356 60200	TipSet Timer XDG
93 190 20080	Mobile stand
<i>Date of Manufacture</i>	Since April 2017

We hereby declare that the above mentioned products meet the provisions of the European Council Directive 93/42/EEC relating to Medical Devices, and subsequent amendments and integrations of which in the Directive 2007/47/EC of the European Parliament and of the Council, as per requirements of Annex II excluding point 4, and are listed in class IIb, according to rule 10 of criteria reported in annex IX of same directive.

The conformity of the Full Quality Assurance System is certified by:

IMQ S.p.a. - Via Quintiliano 43, 20138 Milano, Italy

The identification number of the notified body is 0051.

The standards applied by the Manufacturer are the following:

EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-3:2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN 60601-2-65: 2013	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

Assago, 09 May 2022

Place and Date

FONA S.r.l.

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Mr. Felice Orlando Grandini
 CEO President