FONA
CLOSER TO YOU

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*
97 682 61020	**FONA ART Plus** Panoramic X-Ray systems

made by a combination of the following articles

Type Number	*Article*
84 682 60320	Panoramic Overhead
73 680 00500, 73 680 00800	X-Ray Generator
61 680 07400	Beam Limiting Device
84 6000 00150	Column
93 6000 09000	Self-standing base

Date of Manufacture 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 60601-2-63:2015	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-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 62366-1:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life-cycle processes
IEC 60825-1:2014	Safety of Laser products. Part 1: Equipment classification, requirements and user's guide

FONA S.r.l.
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Assago, 09 May 2022

Place and Date

Mr. Felice Orlando Grandini
CEO President

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