

## 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*  
9380000100, 9380000200,      **StarX-1, StarX-2,**  
9380001100, 9380001200      **StarX PRO-1, StarX PRO-2**  
  
Digital systems for the acquisition of dental images

*Date of Manufacture*      Since November 2020

*This declaration of conformity is issued under the sole responsibility of the manufacturer*

**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 VI, section 3, and are listed in class IIa according to rule 5 of criteria reported in annex IX of same directive.**

*The compliance of the complete Quality Assurance System is certified by:*

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

*The identification number of the notified body is 0051.*

*Certificate n° 1531 / MDD*

The standards applied by the manufacturer are shown below:

<b>EN 62366-1:2015</b>	Medical devices - Application of usability engineering to medical devices
<b>EN 60601-1:2006+A1:2013</b>	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
<b>EN 60601-1-2:2015</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
<b>IEC 62220-1-1:2015</b>	Characteristics of digital X-Ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging.
<b>EN 60601-1-6:2010</b>	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
<b>EN IEC 61223-3-4</b>	Evaluation and routine testing in medical imaging departments - Parts 3 - 4: Acceptance tests-imaging performance of dental X-Ray equipment.

Assago, 09 May 2022

Place and Date

**FONA S.r.l.**

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Felice Orlando Grandini  
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