

EC CERTIFICATE

Certificate No 1531/MDD

Product Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex VI, section 3 of the Directive 93/42/EEC and its revised version, we hereby certify that:

FONA SRL

20057 ASSAGO (MI) - VIA GALILEO GALILEI 11 (ITA) - Italy

manages in the factory of:

20057 ASSAGO (MI) - VIA GALILEO GALILEI 11 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Storage Phosphor Dental imaging plate

Type ref. FONA Dental IP.
Trade mark FONA

Digital radiographic systems

Type ref. StarX-1; StarX-2; StarX PRO-1; StarX PRO-2.

with relevant essential requirements of the aforementioned directive (as far as the final inspection is concerned) and it is subject to surveillance as specified in section 4 of Annex VI. For class IIb devices, this certificate is valid only with relevant EC Type-Examination certificate of Annex III.

Reference to IMQ files Nos:

10AM00043; 10EN00085; 10AO00134; DM16-0000285; DM18-0033269-01; DM20-0056089-01; DM20-0057752-01.

This Approval Certificate is issued by IMQ as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

 Date:
 2012-05-21

 Updated:
 2020-12-17

 Substitution Date:
 2020-11-11

 Expiry Date:
 2024-05-26

IMQ