



EC CERTIFICATE

Certificate No 1436/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, 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:

Panoramic, cephalometric and tomographic X-ray system

Type ref. FONA XPan; FONA XPan DG; FONA XPan DG Plus; FONA ART Plus; FONA ART Plus C; FONA XPan 3D; FONA XPan 3D Plus; Stellaris 3D; Stellaris 3D Ceph.

Trade mark FONA

Type ref. Stellaris 2D; Stellaris 2D Ceph.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AL00059; 10EL00046; COMEDCONMHDM120059304-01; 10AN00016; 10EN00085; DM15A0528920-01; DM16-0000285; DM17-0011712-01; DM18-0033269-01; DM20-0053497-01; DM20-0057752-01; DM20-0059915-01.

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

Date: 2011-05-12
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IMQ