



EC CERTIFICATE

Certificate No 1660/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:

OWANDY RADIOLOGY SAS

77183 CROISSY BEAUBOURG - 2, Rue des Vieilles Vignes (FRA) - France

manages in the factory of:

77183 CROISSY BEAUBOURG - 2, Rue des Vieilles Vignes (FRA) - France

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

Panoramic and cephalometric X-ray systems

Type ref. I-MAX Touch; I-MAX Touch 3D; I-MAX; I-MAX 3D.
Trade mark Owandy Radiology

Digital radiographic systems

Type ref. Opteo; One
Trade mark Owandy Radiology

Dental X-ray systems

Type ref. Ow-RX; Owandy-RX-AC; Owandy-RX-DC.
Trade mark Owandy Radiology

Software for management of dental radiological images

Type ref. QuickVision
Trade mark Owandy Radiology

Devices for recording X-ray imaging for intra oral images

Type ref. Owandy-CR
Trade mark Owandy Radiology

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.

Date: 2014-02-05
Updated: 2020-03-23
Substitution Date: 2019-09-03
Expiry Date: 2024-01-07


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Reference to IMQ files Nos:

10AO00003; 10AO00020; DM15A0536249-01; 10AO00192; DM16-0002178; DM18-0029066-01; DM19-0041901-01; DM20-0048909-01; DM20-0048912-01.

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.

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A handwritten signature in black ink, appearing to be 'F. G.', is written over a horizontal line.

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IMQ