

EC CERTIFICATE

Certificate No 605/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

ODEL SPA

manages in the factories of:

MONZA (MI) - VIA SARTIRANA, 12 (ITA) - Italy

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

High frequency high voltage generator for radiodiagnostic

Series: ENDEAVOUR Type ref. R306.34; R306.35; R306.36

Trade mark ODEL

Series: PROGRAM HF US Type ref. R306.40; R306.41; R306.42; R306.43.

Trade mark ODEL

Control console for radiological generators

Type ref. C306.40; C306.41; C306.42.

Trade mark ODEL

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AC00267 ; 10AE00216; 10AG00040; 10AI00187.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.

Notified Body notified to European Commission under number: 0051.

Date: 2003-01-22

Updated: 2008-10-16

Substitution Date: 2008-01-21



IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2013-01-20 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts