

EC CERTIFICATE

Certificate No 384/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:

I.A.E. INDUSTRIA APPLICAZIONI ELETTRONICHE SPA

manages in the factories of:

CORMANO (MI) - VIA GRAMSCI 57 (ITA) - Italy

CORMANO (MI) - VIA F. FILZI 53 (ITA) - Italy

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

X-ray tube assemblies

Type ref. C52; C352; C52 Super; C100; C339; CE115; CV150; CC100; CG52; CG53; CG100; CP52; C339E; C339C; C339V; C30; CC52; CC50; CC700; C100 XT; C42; CD100.
Trade mark IAE

CT X-ray tube assemblies

Type ref. CE 165 P; CE 165 Z; CE 135 VM; CE 135 J; CE 9800; CE 115; CE 100 CT; CE 135 VP; CE 165 S.
Trade mark IAE

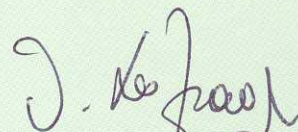
with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AA00277; 10AA00139; 10AC00066; 10AC00228; 10AE00143; 10AE00214; 10AF00057; 10AF00233; 10AF00234; 10AJ00020; 10EJ00013.

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: 2001-03-16
Updated: 2009-07-28
Substitution Date: 2009-02-27


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 2011-02-09 (article 11, clause 11 of the Directive).

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

