

EC CERTIFICATE

Certificate No 385/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:

I.A.E. INDUSTRIA APPLICAZIONI ELETTRONICHE SPA

24121 BERGAMO (BG) - VIA VERDI N. 11 (ITA) - Italy

manages in the factories of:

20032 CORMANO (MI) - VIA GRAMSCI 57 (ITA) - Italy

20032 CORMANO (MI) - VIA F. FILZI 53 (ITA) - Italy

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

X-ray tubes

Type ref. X50; X50 AH; RTM 80 H/HS; RTM 90 H/HS; RTM 92 H/HS; RTM 101 H/HS; RTM 102 H/HS; RTC 600 HS; RTC 700 HS; X20; X20 P; X22; X40; X40 S; X45; RTM 70; RTM 78 H/HS; RTM 780 H; XM12; XM15; X40C; X22 HS; RTM 782 H/HS; RTC 1000 HS; X25; X50 H; RTM 30 HS; RTM 75 H/HS; RTM 77 H/HS; XM1016; RTC 602 HS; XM12 T; XM1016 T; XM15 T; X22 P; RTM 72 H/HS; XM65 T; RTM70 H/HS; X39; X42; RTM 37 HS; X76; F105; F112; F115.

Trade mark IAE

CT X-ray tubes

Type ref. RTC 165; RTM 135; RTM 9800; RTM 117; RTM 103 Max.

Trade mark IAE

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.

Reference to IMQ files Nos: 10AA00277; 10AA00139; 10LD00008; 10AD00245; 10AE00214; 10AF00056; 10AF00187; 10AF00235; 10AI00169; 10EJ00013; 10EK00093; 10AM00069; 10AN00152; DM15E0536056-01.

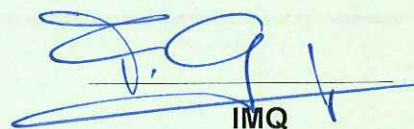
This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.

Notified Body notified to European Commission under number: 0051.

Date: 2001-03-16

Updated: 2015-10-20

Substitution Date: 2014-01-30



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 2020-10-19 (article 11, clause 11 of the Directive).

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