CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1763775 **Master Contract:** 233706

Project: 1763775 **Date Issued:** February 15, 2006

Issued to: **I.A.E. Industria Applicazioni Elettroniche S.p.A.**
Via Fabio Filzi, 53
20032 - Cormano (MI)
ITALY

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

Issued by: O. Ewanchyna, P. Eng.

Authorized by: M.H.J. Hoendervangers

C US

PRODUCTS

8750 01 MEDICAL ELECTRICAL EQUIPMENT
8750 81 MEDICAL ELECTRICAL EQUIPMENT Certified to US Standard

General purpose component type X-ray tube with rotating anode:

Part A: model X20, ratings 130 kVpp; 27 kW max
Part B: model X20 P; X25, ratings 130 kVpp; 17 kW max
Part C: model X22, ratings 130 kVpp; 32 kW max
Part D: models X22 HS; RTM 30 HS, ratings 130 kVpp; 54 kW max
Part E: model X40, ratings 130 kVpp; 40 kW max
Part F: model X40 S, ratings 130 kVpp; 40 kW max
Part G: model X45, ratings 130 kVpp; 40 kW max
Part H: models X50; X50 H, ratings 130 kVpp; 50 kW max
Part I: model X50 AH, ratings 130 kVpp; 50 kW max
Part J: models RTM 70 H; RTM 70 HS, ratings 130 kVpp; 45 kW max
Part K: models RTM 75 H; RTM 75 HS, ratings 150 kVpp; 32 kW max
Part L: models RTM 77 H; RTM 77 HS, ratings 150 kVpp; 72 kW max
Part M: models RTM 78 H; RTM 78 HS, ratings 150 kVpp; 85 kW max
Part N: model RTM 780 H, ratings 150 kVpp; 25 kW max

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards176377February 15, 200233701763775

Part O: models RTM 80 H; RTM 80 HS; RTM 90 H; RTM 90 HS; RTM 782 H; RTM 782 HS, ratings 150 kVpp; 37 kW max
Part P: models RTM 92 H; RTM 92 HS, ratings 150 kVpp; 110 kW max
Part Q: models RTM 101 H; RTM 101 HS, ratings 150 kVpp; 150 kW max
Part R: models RTM 102 H; RTM 102 HS, ratings 150 kVpp; 125 kW max
Part S: model RTC 600 HS, ratings 150 kVpp; 150 kW max
Part T: model RTC 700 HS, ratings 150 kVpp; 150 kW max
Part U: model RTC 1000 HS, ratings 150 kVpp; 150 kW max

Mammography component type X-ray tube with rotating anode:

Part V: model XM12, ratings 40 kVpp; 9 kW max
Part W: model XM15, ratings 40 kVpp; 9 kW max
Part X: model XM1016, ratings 40 kVpp; 4.9 kW max

Note: max power depends both of rotating anode speed and focal spot.

General purpose component type X-ray tube-assemblies:

Part Y: model C30, rating 125 kVpp
Part Z: models C52; C352, rating 150 kVpp
Part AA: model C52 Super, rating 150 kVpp
Part AB: model C100, rating 150 kVpp
Part AC: model C100 XT, rating 150 kVpp

Mammography component type X-ray tube-assemblies:

Part AD: models C339C; C339E; C339V, ratings 40 kVpp

CONDITIONS OF ACCEPTABILITY

Component type X-ray tubes and X-ray tube-assemblies should be installed on general-purpose or mammography radiology units and re-evaluated accordingly in end-use product.

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 0-M91	General Requirements - Canadian Electrical Code, Part II
CAN/CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment Part I: General Requirements for Safety
CAN/CSA-C22.2 No. 601.1S1-94	Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 Medical Electrical Equipment-Part 1: General Requirements for Safety

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CAN/CSA-C22.2 No. 601.1B-98-	Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical Electrical Equipment-Part 1: General Requirement for Safety
CAN/CSA-C22.2 No. 601.1.1-94-	Medical Electrical Equipment-Part 1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
CAN/CSA-C22.2 No. 601.1.3-98	Medical Electrical Equipment- Part I: General; Requirements for Safety –1 Collateral Standard: Safety General Requirement for Radiation Protection in Diagnostic X-ray Equipment
CAN/CSA-C22.2 No. 601.2.28-94	Particular requirements for the safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis.

UL Standards:

UL 60601-1 (1st edition)	-	Medical Electrical Equipment

Subject to the following conditions:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.
(2) Units provided without certified power supply cord sets are certified as components only.
(3) Evaluated to IEC/CSA 601-1 Amendment 2 excluding requirements for Electromagnetic compatibility (Clause 36), Biocompatibility (Clause 48) and Programmable Electronic Systems (IEC 60601-1-4 referenced in sub-clause 52.1).

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Supplement to Certificate of Compliance

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The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
1763775	February 15, 2006	Original Certification for: General purpose component type X-ray tube with rotating anode models X20; X20 P; X25; X22; X22 HS; RTM 30 HS; X40; X40 S; X45; X50; X50 H; X50 AH; RTM 70 H; RTM 70 HS; RTM 75 H; RTM 75 HS; RTM 77 H; RTM 77 HS; RTM 78 H; RTM 78 HS; RTM 780 H; RTM 80 H; RTM 80 HS; RTM 90 H; RTM 90 HS; RTM 782 H; RTM 782 HS; RTM 92 H; RTM 92 HS; RTM 101 H; RTM 101 HS; RTM 102 H; RTM 102 HS; RTC 600 HS; RTC 700 HS; RTC 1000 HS; Mammography component type X-ray tube with rotating anode models XM12; XM15; XM1016; General purpose component type X-ray tube-assemblies models C30; C52; C352; C52 Super; C100; C100 XT; Mammography purpose component type X-ray tube-assemblies models C339C; C339E; C339V.