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Certification Record

Listing#: E114983
Report #: 106055
Original Certification Date: December 18, 2019
Revised Certification Date:

This Certification is issued to:
I.A.E. Industria Applicazioni Elettroniche S.p.A.
Via Verdi, 11-24121
Bergamo, (BG) Italy

Stating that the product(s):
X Ray Tube and X-Ray Tube Assembly and
X Ray Tube and X-Ray Tube Assembly for Mammography
Models; C339; C339E; C339C; C339V; C340V; C341V; XK1016 T, C32; C30; C20; C33, C42, C40; C52; C352; C52 Super; C100; C100 XT; C100 XS; C31, XM12; XM15; XM1016, XM12 T; XM1016 T; XM15 T; XM65 T, F105, F112; F115, X20; X20 P; X22; X25; X39; X40; X40C; X40 S; X42; X45; RTM 30 HS; RTM 37 HS; RTM 70; RTM 70 H/HS; RTM 75 H/HS; RTM 77 H/HS; X22 P, X22 HS, X50; X50 H; X50 AH; X76; RTM 72 H/HS; RTM 76; RTM 78 H/HS; RTM 780 H; RTM 782 H/HS; 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; RTC 1000 HS; RTC 602 HS

Achieved Certification to the following standard(s):
AAMI ES60601-1 - Medical electrical equipment-Part 1: General requirements for basic safety and essential performance - Consolidated Reprint C1: 2009; Incorporating Amendment 1: 2012; Amendment 2: 2010.
CAN/CSA- C22.2 No. 60601-1:14, Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
IEC 60601-2-28/CSA CSA C22.2 NO. 60601-2-28:18 - Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis - Third Edition
IEC 60601-1-3/CSA CSA C22.2 NO. 60601-1-3:09 - Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment - Second Edition

Cedric Valiente

Sr. Project Engineer,
Eurofins MET Labs Safety Laboratory

All changes proposed in the previously identified product that affects the above information must be submitted to Eurofins MET Labs for evaluation prior to implementation to assure continued MET Certification status.

The covered product(s) shall be subject to follow-up inspections to ensure that the Certified product(s) are identical to the product sample evaluated by Eurofins MET Labs and that all manufacturer's responsibilities are being fulfilled as specified in the Manufacturer's Responsibility section of the Certification report. The applicant named above has been authorized by Eurofins MET Labs to represent the product(s) listed in this record as "MET Certified" and to mark this/these product(s) according to the terms and conditions of the MET Applicant Contract, MET Listing Reports, and the applicable marking agreements. Only the product(s) bearing the MET Mark and under a follow-up service are considered to be included in the MET Certification program. This certification has been granted under a System 3 program as defined in ISO/IEC 17067.

Eurofins MET Labs is accredited by OSHA and the Standards Council of Canada.
Eurofins MET Labs – The Nation's First Nationally Recognized Testing Laboratory

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