

**DECLARATION OF CONFORMITY  
EC DIRECTIVE AND CE MARKING**

We, Mirion Technologies (Capintec), Inc.  
7 Vreeland Road Florham Park, NJ 07932 USA  
Phone 201-825-9500 FAX 201-825-1336

declare under our sole responsibility that the CRC-77t Radioisotope Dose Calibrator to which this declaration relates is in conformity with the Medical Device Directive 93/42/EEC.

This product is in conformity with the following standards or other normative documents as follows:

IEC 60601-1-2 (2014) Ed 4: Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1 (2005) Ed3: Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance ;Corr. 1:2006, Corr. 2:2007, Amd. 1:2012

IEC 60601-1-6 (2010) Ed3: Medical Electrical Equipment-Part 1-6: General Requirements for Safety- Collateral Standard: Usability Review of usability per 60601-1 3<sup>rd</sup> Edition.

AAMI ES 60601-1 (2012) Ed3: Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1. Product safety evaluation to AAMI 60601-1 3<sup>rd</sup> Edition, Amendment 1

CSA C22.2 No. 60601-1:(2014), 3rd Edition: Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance

IEC 62304 (2006). Ed. 1 Medical Device Software-Software Life Cycle Processes

IEC 62366 (2007) Ed 1. + A1:2014 Medical Devices-Application of usability Engineering to medical devices

Certified to Annex V of the Directive 93/42/EEC on Medical Devices  
Dose Calibrator, Class I with measuring function  
Certified through Intertek Semko AB, Notified Body MDD

CE mark as show designates conformance to the above statement



The Technical Construction File is maintained at:  
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The authorized representative located within the Community is:  
Atlantico Systems Ltd.  
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Place of Issue:  
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September 15, 2020  
Date of Issue



Vice President, Product Development and Regulatory Affairs