CAPINTEC, INC.
Part of Mirion Technologies

DECLARATION OF CONFORMITY
THE EC DIRECTIVE AND CE MARKING

We, Mirion Technologies (Capintec), Inc.
7 Vreeland Road
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declare under our sole responsibility that the product CRC®-55tR RADIOISOTOPE DOSE CALIBRATOR, CRC®-55tPET RADIOISOTOPE DOSE CALIBRATOR, CRC®-55tW RADIOISOTOPE DOSE CALIBRATOR (including use with Epson Roll and Epson Slip printers) 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:

- IEC 60601-1-2 Ed. 4.0, (2014): Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1:2005, AMD1:2012 Issued: 2012/08/20 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- CAN/CSA-C22.2 No. 60601-1:14: Third Edition Issued: 2014/03/01 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010, AMD1:2013 Issued: 2013/10/29 Ed: 3.1 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 62366-1:2015, Edition 1.1 Issued 2014/01/28 – Medical devices – Application of usability engineering to medical devices
- IEC 62304:2006 + A1:2015 Ed.1.0 Medical device software – Software life cycle processes

Certified to Annex V of the Directive 93/42/EEC on Medical Devices
Dose Calibrators, Class I with measuring function
Certified through Intertek Semko AB, Notified Body MDD
CE 0413
CE Mark as shown denotes conformance to the above statement

The Technical Construction File is maintained at:
Mirion Technologies (Capintec), Inc.
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Phone: (201) 825-9500
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The authorized representative located within the Community is:
Atlantico Systems Ltd.
34 Oldfield, Kingston
Galway, Republic of Ireland

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Place of issue:

Mirion Technologies (Capintec), Inc.
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Mary Anne Yusko
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