CAPINTEC, INC.
Part of Mirion Technologies

DECLARATION OF CONFORMITY
THE EC DIRECTIVE AND CE MARKING

We, Mirion Technologies (Capintec), Inc.
7 Vreeland Road
Florham Park, NJ 07932 USA Phone (800) ASK-4CRC Fax (201) 825-1336

declare under our sole responsibility that the product CRC®-PC SMART CHAMBER (HL, RPh) 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 following:

IEC 60601-1-2 (2014): Medical Electrical Equipment – Part 1 General Requirements for Safety – Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

AAMI ES60601-1 Issued: 2005+A1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance

CAN.CSA-C22.2 No. 60601-1:2014.Ed 3 : Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1 Issued: 2012: Medical electrical equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 2013 Ed. 3.1: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 62366-1:2015. 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 Mark as shown denotes conformance to the above statement.

CE 0413

The Technical Construction File is maintained at:
Mirion Technologies (Capintec), Inc Phone: (800) ASK-4CRC
7 Vreeland Road Fax: (201) 825-1336
Florham Park, NJ 07932

The authorized representative located within the Community is:
Atlantico Systems Ltd.
34 Oldfield, Kingston,
Galway, Republic of Ireland

Place of issue: Date of issue: May 30, 2021
Mirion Technologies (Capintec), Inc
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Mary Anne Yusko

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Vice President, Product Development & Regulatory Affairs

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