# EC CERTIFICATION

## PRODUCTION QUALITY ASSURANCE

### Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements - has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

**Organization:**

# Mirion Technologies (Capintec), Inc

Main Site: 7 Vreeland Road, Florham Park, New Jersey 07932 United States

**Product Category:**

- Dose calibrators, class I with measuring function.

For further identification of the products covered, see the MDD product list/product schedule.

**Certificate Number:**
41313219-04

**Initial Certification Date:**
8 December 2000

**Certificate Valid from:**
9 December 2020

**Certificate Expiry Date:**
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

**Bob Andersson**
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

10 November 2020
**Signed Date**

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

# MDD – Product List

Products included in the certificate no: 41313219-04

Issued to: **Mirion Technologies (Capintec), Inc**
7 Vreeland Road,
Florham Park, New Jersey 07932
United States

| Product category | Type/Model designation | Class | Measuring | GMDN code (not mandatory) | Date added |
|---|---|---|---|---|---|
| Dose Calibrator | | | | | |
| | CRC-55tR | I | Yes | - | Sept 9, 2010 |
| | CRC-55tW | I | Yes | - | Sept 9, 2010 |
| | CRC-55tPET | I | Yes | - | Sept 9, 2010 |
| | The CRC-77t | I | Yes | 40738 | Sept 16, 2016 |
| | The CRC-PC Smart Chamber | I | Yes | 40738 | Dec 4, 2015 |

* Products added before September 9, 2010.

Signed Date: 10 November 2020
Valid Date: 9 December 2020

**Intertek Semko AB**
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.intertek.se
Registered in Sweden: No SE556024059901, Registered office: As address

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