EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects relating to the conformity of the devices with metrological requirements - has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620185244

Revision:
00

Initial Certification Date:
27 August 2024

Date of Certification Decision:
27 August 2024

Certificate Issue Date:
27 August 2024

Certificate Expiry Date:
9 December 2028

Mirion Technologies (Capintec), Inc

7 Vreeland Road, Florham Park, New Jersey 07932 United States

Manufacturer SRN: US-MF-000000770

Authorised Representative Name
Atlantico Systems, Ltd.
34 Oldfield, H91 D8CX Galway, Ireland

Scope:

Metrology aspects of devices as detailed in attached product list.

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2021-477000**
	Stage 2 audit ACTY-2021-477001

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620185244

Revision:
00

Initial Certification Date:
27 August 2024

Date of Certification Decision:
27 August 2024

Certificate Issue Date:
27 August 2024

Certificate Expiry Date:
9 December 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

Issued to: Mirion Technologies (Capintec), Inc

Certificate number: 28620185244

Certificate valid from: 2024-08-27

Product List Issue Date:
27 August 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Dose calibrators, class I with measuring function			
Basic UDI-DI: Not yet provided			
5130-2216 - CRC 55tW Dose Calibrator	Class I(m)		2024-08-27
5130-30253 - CRC PC Smart Chamber HL Chamber	Class I(m)		2024-08-27
5130-30254 - CRC PC Smart Chamber RPh Chamber	Class I(m)		2024-08-27
5130-30255 - CRC PC Smart Chamber HL System	Class I(m)		2024-08-27
5130-30256 - CRC PC Smart Chamber RPh System	Class I(m)		2024-08-27
5130-30261 - CRC 77tHR Dose Calibrator	Class I(m)		2024-08-27
5130-3234 - CRC 55tR Dose Calibrator	Class I(m)		2024-08-27
5130-3235 - CRC 55tPET Dose Calibrator	Class I(m)		2024-08-27

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.