

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 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 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.

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:

- Thyroid Uptake Systems

Certificate Number:

28620196653

Revision:

00

Initial Certification Date:

20 November 2024

Certificate Decision Date:


20 November 2024

Certificate Issue Date:

20 November 2024

Certificate Expiry Date:

9 December 2028



Mikael Hagelin
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

Technical Assessment Report Reference	TD00091-001 Captus 4000e Thyroid Uptake and Well System (2 inch)
Audit Report Reference	Stage 1 audit ACTY-2021-477000
	Stage 2 audit ACTY-2021-477001
	Surveillance 1 audit ACTY-2021-477004

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620196653	20 November 2024	Initial Certificate



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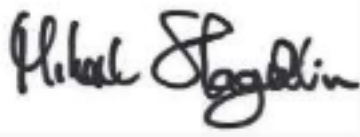


PRODUCT LIST FOR CERTIFICATE

Issued to: Mirion Technologies (Capintec), Inc
Certificate number: 28620196653
Certificate valid from: 2024-11-20

Product List Issue Date:
20 November 2024

Product	Classification and EMDN	Intended use ¹	Date Added
Thyroid Uptake Systems			
<i>Basic UDI-DI: 085994200610145</i>			
5430-30151 - Captus 4000e Thyroid Uptake System	Class IIa Z11029001	Perform Thyroid Uptakes	2024-11-20
5430-30152 - Captus 4000e Thyroid Uptake and Well System (1 inch)	Class IIa Z11029001	Perform Thyroid Uptakes	2024-11-20
5430-30154 - Captus 4000e Thyroid Uptake and Well System (2 inch)	Class IIa Z11029001	Perform Thyroid Uptakes	2024-11-20



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

