Medicines & Healthcare products Regulatory Agency

Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

ATLANTICO SYSTEMS LTD
3, Wellington Park
Belfast
BT9 6DJ
Northern Ireland, United Kingdom

22 February 2024

Dear **Sheena Bond**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **21 February 2024** has been reviewed:

Application reference: **2024022101344218**

Manufacturer organisation: **Mirion Technologies (Capintec), Inc**
Address:
7 Vreeland Road
New Jersey
Florham Park
07932
United States

Manufacturer registration status: **Registered**

Device(s):

GMDN Code & Term	Status	Comment
40648 - Thyroid-uptake nuclear medicine system	Registered	

GMDN Code & Term	Status	Comment
33115 - Nuclear medicine phantom, anthropomorphic	Registered	
40738 - Radioisotope calibration system	Registered	
38379 - Syringe radiation shield	Registered	
38380 - Vial radiation shield	Registered	
40630 - Nuclear medicine phantom, test object	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000030953.**

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
Medicines and Healthcare products Regulatory Agency