

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

| MANUFACTURER | | | |
|---|--|--|--|
| Name of Company | | Address | SRN |
| Mirion Technologies (Capintec), Inc. | | 7 Vreeland Road, Florham Park, NJ 09732 USA | US-MF-000000770 |
| AUTHORIZED REPRESENTATIVE | | | |
| Name of Company | Address | SRN | Telephone/fax/email |
| Atlantico Systems, Ltd. | 34 Oldfield, Galway, Ireland | IE-AR-000000208 | +35391443609/ info@AtlanticoSystems.com |
| PRODUCT IDENTIFICATION | | | |
| Product Name | Product Code / Catalog Number | | Basic UDI-DI |
| Vial Shields | See product list on page 2 of Declaration of Conformity | | 08599420061034W |
| Intended Purpose | | | Photo |
| Vial Shields are radiation protection devices used in the preparation and dispensing of radiopharmaceuticals. | | | NA |
| RISK CLASS FOR MEDICAL DEVICES | | | |
| Device Classification | Common Specifications | | |
| Class: I Rule: 1, Annex VIII | NA | | |
| NOTIFIED BODY | | | |
| Name of Company | ID Number | Conformity Assessment Procedure | Certificate Reference(s) |
| NA | | | |

Autograph declares that the above-mentioned products meet the provision of the following EU legislation:

MDR (EU) 2017/745

COMPANY REPRESENTATIVE: Mary Anne Yusko
TITLE: Vice President, Regulatory Affairs



SIGNATURE:

DATE: November 1, 2021

PLACE: Mirion Technologies (Capintec), Inc.
7 Vreeland Road
Florham Park, NJ 09732 USA

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Vial Shield Family Product List

| Product Name | Model # |
|---|---------|
| High Density Lead Glass Vial Shield | 001-075 |
| Vial Pig | 001-706 |
| Vial Shield, Intego | 001-708 |
| Vial Shield, Lead | 001-236 |
| Vial Shield, Dose Drawing, PET, 30 ml | 001-855 |
| Vial Shield, Dose Drawing, PET, 50 ml | 001-888 |
| Vial Shield, 50 ml | 001-950 |
| Lead Vial Shield with Magnetic Cap | 053-610 |
| Lead Vial Shield with Magnetic Cap with Glass | 053-611 |
| Tungsten Vial Shield with Magnetic Cap | 053-806 |
| Tungsten Vial Shield | 053-807 |