

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
Syringe Shields	See product list on page 2 and 3 of Declaration of Conformity		08599420061024U
Intended Purpose			Photo
Syringe 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: October 1, 2021

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

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Syringe Shield Family Product List

Product Name	Model #	Product Description
Pro-Tec II	007-800	SHIELD, SYRINGE, 3cc, PRO-TEC II
	007-801	SHIELD, SYRINGE, 3cc, PRO-TEC II, W/O GLASS
	007-900	SHIELD, SYRINGE, 5cc, PRO-TEC II
	007-901	SHIELD, SYRINGE, 5cc, PRO-TEC II, W/O GLASS
Pro-Tec III	007-723	SHIELD, SYR, 1cc, PRO-TEC III, (BD LUER LK)
	007-734	SHIELD, SYRINGE, 1cc, PRO-TEC III
	007-735	SHIELD, SYRINGE, 3cc, PRO-TEC III
	007-736	SHIELD, SYRINGE, 5cc, PRO-TEC III
	007-738	SHIELD, SYRINGE, 10cc, PRO-TEC III
	007-755	SHIELD SYRINGE, 2.5cc, PRO-TEC III
Pro-Tec IV	007-670	SHIELD, SYRINGE, 1cc, PRO-TEC IV
	007-675	SHIELD, SYRINGE, 3cc, PRO-TEC IV
	007-680	SHIELD, SYRINGE, 5cc, PRO-TEC IV
	007-685	SHIELD, SYRINGE, 10cc, PRO-TEC IV
Beta	007-956	SHIELD, SYRINGE, BETA, 1cc
	007-957	SHIELD, SYRINGE, BETA, 10cc
	007-958	SHIELD, SYRINGE, BETA, 20cc
Dose Drawing	007-661	SHIELD, SYRINGE, 3cc, DOSE DRAWING
	007-663	SHIELD, SYRINGE, 5/6cc, DOSE DRAWING
	007-665	SHIELD, SYRINGE, 10/12cc, DOSE DRAWING
	007-691	SHIELD, SYRINGE, 3cc DOSE DWG, NON-LUER
	007-693	SHIELD, SYRINGE, 5/6cc, DOSE DWG, NON-LUER
	007-695	SHIELD, SYRINGE, 10/12cc, DOSE DWG, LUER
Double-Ended PET Pig	001-793	PIG, DOUBLE ENDED, PET, .6" LEAD
High Density Lead Glass	007-612	SHIELD, SYRINGE, 10/12cc, LUER/NON-LUER
	007-620	SHIELD, SYRINGE, 1cc, LUER/NON-LUER
	007-635	SHIELD, SYRINGE, 3cc, LUER/NON-LUER
	007-652	SHIELD, SYRINGE, 5/6cc, LUER/NON-LUER
PET	007-969	SYRINGE SHLD, PRO-TEC PET, 5cc, HSW
	007-973	SYRINGE SHLD, PRO-TEC PET W/GLASS, 3cc
	007-975	SYRINGE SHLD, PRO-TEC PET W/GLASS, 5cc
	007-980	SYRINGE SHLD, PRO-TEC PET W/GLASS, 10cc
	007-983	SYRINGE SHLD, PRO-TEC PET W/O GLASS, 1cc
	007-985	SYRINGE SHLD, PRO-TEC PET W/O GLASS, 3cc
	007-990	SYRINGE SHLD, PRO-TEC PET W/O GLASS, 5cc



	007-995	SYRINGE SHLD,PRO-TEC PET W/O GLASS, 10cc
	007-984	SYRINGE SHIELD, PET DOSE DWG, 5cc, TUNG
	007-986	SYRINGE SHIELD, PET DOSE DWG, 3cc, TUNG
PET/MR	007-961	SYRINGE SHIELD, PET/MRI, W/GLASS, 3cc
	007-962	SYRINGE SHIELD, PET/MRI, W/GLASS, 5cc
	007-966	SYRINGE SHIELD, PET/MRI, W/o GLASS, 3cc
	007-967	SYRINGE SHIELD, PET/MRI, W/o GLASS, 5cc
PET Guard Lock	007-711	SYRINGE SHIELD, GAARD LOCK, PET, 3cc
	007-712	SYRINGE SHIELD, GAARD LOCK, PET, 5cc
	007-713	SYRINGE SHIELD, GAARD LOCK, PET, 10cc
	007-716	SYRINGE SHLD, GAARD LOCK, PET, 3cc,W/GLS
	007-717	SYRINGE SHLD, GAARD LOCK, PET, 5cc,W/GLS
	007-718	SYRINGE SHLD, GAARD LOCK, PET,10cc,W/GLS
Z-PET	007-945	SYRINGE, SHIELD, Z-PET, 5cc
Syringe Carriers	001-179	SYRINGE CARRIER, LARGE, .125" LEAD
	001-180	SYRINGE CARRIER, LARGE, .25" LEAD
	001-181	SYRINGE CARRIER, SMALL, .125" LEAD
	001-182	SYRINGE CARRIER, SMALL, .25" LEAD
	009-205	SYRINGE CARRIER, SINGLE, 0.25"-0.5" LEAD