CAPINTEC, INC.
A Mirion Technologies company

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**
Bar Phantoms	243-800 Phantom, Bar, Standard, High Resolution 243-815 Phantom, Bar, G.E. 243-816 Phantom, Bar, G.E. 243-935 Phantom, Bar, Rectangle 243-955 Phantom, Bar, Cardiac 243-987 Phantom, Bar, E-Can & Symbia, 21"x16"	08599420061044Y

Intended Purpose	Photo
The Bar Phantom is a radionuclide test pattern phantom and is intended to be used as a quality assurance device to verify the intrinsic resolution, collimator spatial resolution, field size, and linearity of a gamma camera.	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 (LVFS 2003:11 as amended by LVFS 2009:07)

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

SIGNATURE: Mary Anne Yusko

DATE: August 18, 2021

PLACE: Mirion Technologies (Capintec), Inc.
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Florham Park, NJ 07932 USA

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