CAPINTEC
A MIRION MEDICAL 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 Number**	
Table, Urology C-Arm-800,115VAC	058-800	
Table, Urology C-Arm-800, 230 VAC	058-805	
Table, Brachytherapy C-Arm, 115 VAC	058-810	
Table, Brachytherapy C-Arm, 230 VAC	058-815	
Table, 3-D Imaging C-Arm, 115 VAC	058-820	
Table, 3D Imaging, C-Arm, 230 VAC	058-825	
Table, Surgical C-arm, Contour 115VAC	058-840	
Table, Surgical C-arm, Rectangle top, 115VAC	058-840-10	
Table, Surgical C-Arm, 230 VAC	058-845	
Table, Surgical C-Arm, Rectangle Top, 230 VAC	058-845-10	
Table, Surgical C-Arm, Contour, 115 VAC	058-846	
Table, Surgical C-Arm, Rectangle, 115 VAC	058-846-10	
Table, Surgical C-Arm, Contour, 230 VAC	058-847	
Table, Surgical C-Arm, Rectangle, 30 VAC	058-847-10	
Table, Pain Management C-Arm, 115VAC	058-870	
Table, Pain Management C-Arm, Rectangular Top, 115VAC	058-870-10	
Table, Pain Management C-Arm, 230VAC	058-875	
Table, Pain Management C-Arm, Rectangular Top, 230VAC	058-875-10	

Intended Purpose	Basic UDI/EMDN
The Surgical C-Arm Tables are intended as patient tables for use with a variety of image-guided procedures using portable or ceiling mounting C-Arm Fluoroscopy systems.	85994200610756/ Z12011202

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Standards**
Class: I Rule: 13, Annex	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010 CAN/CSA-C22.2 No. 60601-1:2014 IEC 60601-2-46 Edition 3.0 CAN/CSA-22.2 No. 60601-2-46:12 IEC 60601-1-2:2014

NOTIFIED BODY			
Name of Company	**ID Number**	**Address**	**Certificate Reference(s)**
N/A			

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: Director, Regulatory Affairs

SIGNATURE: Mary Anne Yusko _____ **DATE:** April 15, 2023

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