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

Name of Company	**Address**	**SRN**
Atlantico Systems, Ltd.	34 Oldfield, Galway, Ireland	IE-AR-000000208

PRODUCT IDENTIFICATION	
Product Name	**Product Number**
Sound Pro Combination Ultrasound Table	058-710
Ultra Pro Ultrasound Table	058-720
Econo Ultrasound Table	058-726
Echo Pro Echocardiography Table	058-700
Econo Echocardiography Table	058-701
EchoVasc Pro Vascular Echocardiology Table	058-702
Vasc Pro Vascular Ultrasound Table	058-732
Ultra Pro Ultrasound Table 230V	058-725
Echo Pro Echocardiography Table 230V	058-705
Echo/Vasc Pro Table 230V	058-707
Sound Pro Combination Ultrasound Table 230V	058-715
Econo Ultrasound Table 230V	058-727
Vasc Pro Vascular Ultrasound Table 230V	058-733
Econo Echocardiography Table 230V	058-706

Intended Purpose	**Basic UDI/EMDN**
The Ultrasound family of tables are intended as patient tables for use with a variety of general ultrasound head and torso procedures including echocardiography, OB/GYN, and vascular procedures. They are ergonomically designed for comfort of patient and sonographer.	85994200610858/ Z1104018099

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Standards**
Class: I Rule: 13, Annex VIII Conformity Assessment per Annex IX	EC 60601-1-2:2014+A1:2020 (ed 4.1) Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 60601-1:2005+A1:2012+A2:2020 Ed 3.2 Medical Electrical Equipment. Part 1. General Requirements for Basic Safety and Performance. ANSI/AAMI ES60601-1:2005+A1:2012+A2:2020 Issued: 2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance CAN/CSA-C22.2 No. 60601-1:14/A2-2022: (2022) – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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:** January 20, 2024

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