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 Code / Catalog Number**	**Basic UDI-DI/EMDN**
Captus 4000e Thyroid Uptake System Captus 4000e Thyroid Uptake and Well System (1 in) Captus 4000e Thyroid Uptake and Well System (2 in)	5430-30151 5430-30152 5430-30154	08599420061014S/ Z11029001

Intended Purpose	Photo
The Captus 4000e Thyroid Uptake System is intended to be used to perform thyroid uptake tests.	NA

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Standards**
Class: IIa Rule: 10, Annex VIII Conformity Assessment per Annex IX	IEC 60601-1-2 Ed. 4.1, (2020-09): 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 ED 4+A1;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: Third Edition Issued: 2014/03/01 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 +A1;A2 2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability IEC 62366:2014, Edition 1.1 Issued 2014/01/28 – Medical devices – Application of usability engineering to medical devices IEC 62304:2006 + A1:2015 issued Medical device software – Software life cycle processes

NOTIFIED BODY			
Name of Company	**ID Number**	**Address**	**Certificate Reference(s)**
Intertek Medical Notified Body AB	2862	Torshamnsgatan 43 Box 1103, SE-164 22 Kista, Sweden	28620196653

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: November 20, 2024

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