CAPINTEC, INC.
Part of Mirion Technologies

DECLARATION OF CONFORMITY
THE EC DIRECTIVE AND CE MARKING

We, Mirion Technologies (Capintec), Inc.
7 Vreeland Road, Florham Park, NJ 07932 USA
Phone (201) 825-9500 Fax (201) 825-1336

declare under our sole responsibility that the product CAPTUS 4000e THYROID UPTAKE SYSTEM, all models (including use with the Hewlett-Packard Officejet printer) to which this declaration relates is in conformity with the MDD 93/42/EEC as transposed into Swedish national law LVFS 2003:11. Models include 5430-30151, 5430-30152, 5430-30154, 5430-00007.

This product is in conformity with the following standards or other normative documents following:

- IEC 60601-1-2:2014 Ed. 4.1 + A1:2020: 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, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020:Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- CAN/CSA-C22.2#60601-1:2014 Ed.3+A2 2022 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 Ed.3+A1;A2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 62366-1:2015 Ed 1 + A1 – Medical devices – Application of usability engineering to medical devices
- IEC 62304:2006 Ed.1 + A1:2015 issued Medical device software – Software life cycle processes

Certified to Annex II of the Directive 93/42/EEC on Medical Devices
Thyroid Uptake Systems, Class IIa
Certified through Intertek Semko AB, Notified Body MDD
CE Mark as shown denotes conformance to the above statement.

CE 0413

The Technical Construction File is maintained at:
Mirion Technologies (Capintec), Inc. Phone (201) 825-9500
7 Vreeland Road Fax: (201) 825-1336
Florham Park, NJ 07932

The authorized representative located within the Community is:
Atlantico Systems Ltd.
34 Oldfield, Kingston, Galway, Republic of Ireland

Place of issue: Date of issue: April 30, 2024
Mirion Technologies (Capintec), Inc.
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Phone (201) 825-9500 Fax (201) 825-1336

Mary Anne Yusko

Mary Anne Yusko
Director, Product Development & Regulatory Affairs

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