

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Ivy Biomedical Systems, Inc.

(FIN F000856)

Main Site: 11 Business Park Drive,

Branford, Connecticut 06405 United States

has been registered by Intertek, an MDSAP recognised auditing organisation,  
as conforming to the requirements of:

### ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

The design, development, manufacture and service of physiological monitors of vital signs including cardiac trigger monitors and modules.

**Certificate Number:**

0074695-04

**Initial Certification Date:**

2018-04-25

**Date of Certification Decision:**

2024-03-20

**Certification Effective Date:**

2024-04-24

**Certification Expiry Date:**

2027-04-24



**intertek**

**Calin Moldovean**

President, Business Assurance

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