

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: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

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:

0074695-03

Initial Certification Date:

2018-04-25

Date of Certification Decision:

2022-04-15

Certification Effective Date:

2022-04-15

Certification Expiry Date:

2024-04-24



intertek

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