EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620150777

Revision:
00

Initial Certification Date:
31 May 2023

Certificate Decision Date:
31 May 2023

Certificate Issue Date:
31 May 2023

Certificate Expiry Date:
28 April 2028

Ivy Biomedical Systems, Inc.

11 Business Park Drive, Branford, Connecticut 06405, United States

Manufacturer SRN: US-MF-000001164

Authorised Representative Name

Emergo Europe B.V

Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Scope:

Physiological monitors, class IIb for ECG monitoring.

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00009-01 Ivy Biomedical Systems, Inc. Cardiac Trigger Monitor**
Audit Report Reference	**Stage 1 audit ACTY-2018-279032**
	Stage 2 audit ACTY-2020-438584
	DELTA stage 2 repeated ACTY-2023-638659

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620150777

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MDR – Decision Report

Certificate No: 28620150777
Date: 31 May 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Ivy Biomedical
Attn: Felicia Piel
11 Business Park Drive
Branford, Connecticut 06405
United States

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2018-279032	Branford	Alexander Crosby	23 Jul 2021
Stage 2 ACTY-2020-438584	Branford	Alexander Crosby	8 – 9 Sep 20201
DELTA stage 2 repeated ACTY-2023-638659	Branford	Alexander Crosby	13 – 14 April 2023

Technical Documentation Report	Assessor Name	Assessment Date
Technical Report – IVY Biomedical – Cardiac Trigger Monitor – 2022-12-19 BPW	Ben Wall	19 Dec 2022
CEAR – IVY Biomedical TD000009-01 2022-12-08	Ben Wall	8 Dec 2022
Request for Additional Information – IVY Biomedical – Cardiac Trigger Monitor – 2022-12-09 BPM	Ben Wall	9 Dec 2022

Scope of assessment

Physiological monitors, class IIb for ECG monitoring., Class

Result

0 non conformities were noted during the audit.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Valid from

31 May 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

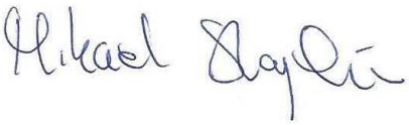
Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (TD Assessment)



Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Ivy Biomedical Systems, Inc.

Certificate number: 28620150777

Certificate valid from: 2023-05-31

Product List Issue Date:
31 March 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Vital sign monitoring devices			
Basic UDI-DI: 0816396027000_SeriesRE			
Model 7600 - Cardiac Trigger Monitor	Class IIb Z120302	The Ivy Biomedical Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate.	2023-05-31
Model 7600EP - Cardiac Trigger Monitor	Class IIb Z12030299	The Ivy Biomedical Model 7600EP/7800EP is a basic cardiac monitor used to provide cardiac trigger pulse outputs used by third-party diagnostic imaging systems that require ECG synchronization, such as nuclear medicine, computed axial (CAT), or positron emission (PET) tomography, and other imaging systems requiring similar cardiac cycle specific timing. The Ivy Biomedical Model 7600EP/7800EP monitors can also be used to provide cardiac trigger pulse outputs used by thirdparty ablation and lithotripsy systems.	2023-05-31
Model 7700 - Cardiac Trigger Monitor	Class IIb Z120302	The Ivy Biomedical Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate.	2023-05-31
Model 7800 - Cardiac Trigger Monitor	Class IIb Z120302	The Ivy Biomedical Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate.	2023-05-31
Model 7800EP - Cardiac Trigger Monitor	Class IIb Z12030299	The Ivy Biomedical Model 7600EP/7800EP is a basic cardiac monitor used to provide cardiac trigger pulse outputs used by third-party diagnostic imaging systems that require ECG synchronization, such as nuclear medicine, computed axial (CAT), or positron emission (PET) tomography, and other imaging systems requiring similar cardiac cycle specific timing. The Ivy Biomedical Model 7600EP/7800EP monitors can also be used to provide cardiac trigger pulse outputs used by thirdparty ablation and lithotripsy systems.	2023-05-31
Model 7810 - Cardiac Trigger Monitor	Class IIb Z120302	The Ivy Biomedical Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate.	2023-05-31

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.