



EU Declaration of Conformity

(Following the provisions of EU Medical Device Regulation, 2017/745, EMC directive 2014/30/EU, and RoHS directive 2011/65/EU)

Common Information

Manufacturer	Ivy Biomedical Systems, Inc. 11 Business Park Drive Branford, CT 06405 USA
Manufacturer's SRN	US-MF-000001164
EU Authorized Representative	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands
EU Authorized Representative's SRN	NL-AR-000000116
Swiss Authorized Representative	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland
Swiss Authorized Representative's CHRN	CHRN-AR-20001035

Medical Device Regulation (2017/745 as amended by 2023/607)

A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer	This Declaration of Conformity is issued under the sole responsibility of Ivy Biomedical Systems, Inc.
Product and trade name	Model 7000 Series Cardiac Trigger Monitor
Intended Purpose:	The Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate. They are designed for use in the ICU, CCU and operating room conditions. They can sound an alarm when HR falls outside of preset limits. They provide an output pulse, synchronized to the R-wave for use in applications requiring precision R-wave synchronization. The Model 7810 also provides a secondary output pulse synchronized to chest wall motion due to respiratory effort.
Product Part Number(s) and Description(s)	Refer to Appendix A
Basic UDI-DI	0816396027000 SeriesRE
Product Code (EMDN, MDA)	Z120302, MDA 0203
Risk class of the device	Class IIb according to Annex VIII, Rule 10
A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity	The device in this declaration conforms with EU Regulation 2017/745 (MDR) and other relevant Union legislation.
References to any CS used and in relation to which conformity is declared	No CS used for conformity
The name of the Notified Body	Intertek Medical Notified Body AB
Identification number of the Notified Body	2862
A description of the conformity assessment procedure performed	EU Regulation 2017/745, Annex IX Chapters I & III

Identification of the certificates issued	Quality Management System Certificate Number: 28620150777 EN ISO 13485:2016 Certificate No: 0113294-02
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EMC Directive (2014/30/EU)

Product	Model 7000 Series Cardiac Trigger Monitor
Statement	This Declaration of Conformity is issued under the sole responsibility of the Manufacturer, Ivy Biomedical Systems, Inc. The fulfilment of the essential requirements set out in Annex I has been demonstrated
Object of the declaration	The object of the declaration described above is in conformity with the relevant Union harmonization legislation
The relevant harmonized standards used	NA
References to the other technical specifications used	NA
Notified Body Name and Number	NA
Description of Intervention	NA
Certificate Issued	NA

RoHS Directive (2011/65/EU as amended by 2015/863)

Unique identification of the EEE	Model 7000 Series Cardiac Trigger Monitor
Statement	This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Ivy Biomedical Systems, Inc. It has been demonstrated that the requirements specified in Article 4 have been met.
Object of the declaration	The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Relevant harmonized standards used	EN IEC 63000:2018
Relevant technical specifications used	N/A

Declaration of Conformity Issued

Place of issue	Branford, CT	
Issued on behalf of	Ivy Biomedical Systems, Inc.	
Function of the person signing	VP, Quality Assurance/Regulatory Affairs	
Name of the person signing		
		
Felicia Piel <i>Printed Name</i>	<i>Signature</i>	23-Jan-2024 <i>Date of Issue</i>

APPENDIX A

Product Part Number(s) and Description(s)

R=Recorder, NR=No Recorder, MT=Mounting Plate, NMT= No Mounting Plate

Variant's Part Number	Description	UDI-DI
7600 Cardiac Trigger Monitor		
3299-00-15	FINAL ASSY,7600-R/MT	00816396021976
3299-01-15	FINAL ASSY,7600-R/MT	00816396020948
3299-02-15	FINAL ASSY,7600-NR/MT	00816396020955
3299-03-15	FINAL ASSY,7600-NR/MT	00816396020962
3299-04-15	FINAL ASSY,7600-R/MT	00816396020979
3299-05-15	FINAL ASSY,7600-NR/NMT	00816396020986
3299-06-15	FINAL ASSY,7600-R/NMT	00816396020993
3299-07-15	FINAL ASSY,7600-R/MT	00816396021006
3299-08-15	FINAL ASSY,7600-NR/NMT	00816396021013
3299-09-15	FINAL ASSY,7600-NR/MT	00816396021020
3299-12-15	FINAL ASSY,7600-NR/MT	00816396021044
3299-13-15	FINAL ASSY,7600-NR/NMT	00816396021051
3299-14-15	FINAL ASSY,7600-NR/NMT	00816396021068
3299-16-15	FINAL ASSY,7600-R/NMT	00816396021075
3299-17-15	FINAL ASSY,7600-R/NMT	00816396021082
3299-18-15	FINAL ASSY,7600-NR/NMT	00816396021099
3299-20-15	FINAL ASSY,7600-R/NMT	00816396021112
3299-21-15	FINAL ASSY,7600-R/NMT	00816396021129
3299-24-15	FINAL ASSY,7600-NR/NMT	00816396021150
3299-25-15	FINAL ASSY,7600-R/MT	00816396021167
3299-26-15	FINAL ASSY,7600-NR/MT	00816396021174
3299-28-15	FINAL ASSY,7600-NR/NMT	00816396021198
3299-32-15	FINAL ASSY,7600-NR/MT	00816396021938
3299-33-15	FINAL ASSY,7600-R/MT	00816396021952
3299-34-15	FINAL ASSY,7600-R/MT	00816396021945
3299-35-15	FINAL ASSY,7600-NR/MT	00816396022119
3299-36-15	FINAL ASSY,7600 R/NMT	00816396022461
3299-37-15	FINAL ASSY,7600-NR/NMT	00816396022744
3299-44-15	FINAL ASSY,7600-R/NMT	00816396023185
7600EP Cardiac Trigger Monitor		
3299-38-15	FINAL ASSY,7600EP-NR/NMT	00816396022867
3299-39-15	FINAL ASSY,7600EP-R/NMT	00816396022874
3299-40-15	FINAL ASSY,7600EP-NR/MT	00816396022881
3299-43-15	FINAL ASSY,7600EP-R/NMT	00816396020740
3299-45-15	FINAL ASSY,7600EP-NR/NMT	00816396023208
7800 Cardiac Trigger Monitor		
3300-00-15	FINAL ASSY,7800-R/MT	00816396021228
3300-01-15	FINAL ASSY,7800-R/MT	00816396021235
3300-02-15	FINAL ASSY,7800-R/MT	00816396021242
3300-03-15	FINAL ASSY,7800-NR/MT	00816396021259
3300-05-15	FINAL ASSY,7800-R/MT	00816396021266
3300-06-15	FINAL ASSY,7800-NR/MT	00816396021273
3300-07-15	FINAL ASSY,7800-R/MT	00816396021280
3300-09-15	FINAL ASSY,7800-R/MT	00816396021297
3300-10-15	FINAL ASSY,7800-R/NMT	00816396021525
3300-11-15	FINAL ASSY,7800-NR/NMT	00816396021303
3300-14-15	FINAL ASSY,7800-NR/MT	00816396021327
3300-15-15	FINAL ASSY,7800-R/MT	00816396021334
3300-17-15	FINAL ASSY,7800-R/NMT	00816396021358

Variant's Part Number	Description	UDI-DI
3300-19-15	FINAL ASSY,7800-NR/MT	00816396021372
3300-20-15	FINAL ASSY,7800-R/MT	00816396021389
3300-21-15	FINAL ASSY,7800-NR/NMT	00816396022126
3300-22-15	FINAL ASSY,7800-NR/MT	00816396022218
3300-23-15	FINAL ASSY,7800-NR/MT	00816396022355
7800EP Cardiac Trigger Monitor		
3300-28-15	FINAL ASSY,7800EP-NR/NMT	00816396022935
3300-29-15	FINAL ASSY,7800EP-NR/NMT	00816396023062
7810 Cardiac Trigger Monitor		
3559-00-15	FINAL ASSY,7810-R/MT	00816396021396
3559-01-15	FINAL ASSY,7810-R/MT	00816396021532
3559-02-15	FINAL ASSY,7810-R/MT	00816396021549
7600 Cardiac Trigger Monitor plus Accessory Kit		
3303-00-15	MODEL 7600 MONITOR	00816396021983
3303-01-15	MODEL 7600 MONITOR	00816396020009
3303-02-15	MODEL 7600 MONITOR	00816396020016
3303-03-15	MODEL 7600 MONITOR	00816396020023
3303-04-15	MODEL 7600 MONITOR	00816396020030
3303-05-15	MODEL 7600 MONITOR	00816396020047
3303-06-15	MODEL 7600 MONITOR	00816396020054
3303-07-15	MODEL 7600 MONITOR	00816396020061
3303-08-15	MODEL 7600 MONITOR	00816396020078
3303-09-15	MODEL 7600 MONITOR	00816396020085
3303-10-15	MODEL 7600 MONITOR	00816396020092
3303-12-15	MODEL 7600 MONITOR	00816396020108
3303-14-15	MODEL 7600 MONITOR	00816396020115
3303-15-15	MODEL 7600 MONITOR	00816396020122
3303-19-15	MODEL 7600 MONITOR	00816396020146
3303-20-15	MODEL 7600 MONITOR	00816396020153
3303-21-15	MODEL 7600 MONITOR	00816396020160
3303-22-15	MODEL 7600 MONITOR	00816396020177
3303-23-15	MODEL 7600 MONITOR	00816396020184
3303-24-15	MODEL 7600 MONITOR	00816396020191
3303-25-15	MODEL 7600 MONITOR	00816396020207
3303-26-15	MODEL 7600 MONITOR	00816396020214
3303-27-15	MODEL 7600 MONITOR	00816396020221
3303-28-15	MODEL 7600 MONITOR	00816396020238
3303-29-15	MODEL 7600 MONITOR	00816396020245
3303-30-15	MODEL 7600 MONITOR	00816396020252
3303-31-15	MODEL 7600 MONITOR	00816396020269
3303-32-15	MODEL 7600 MONITOR	00816396020276
3303-33-15	MODEL 7600 MONITOR	00816396020283
3303-35-15	MODEL 7600 MONITOR	00816396020306
3303-37-15	MODEL 7600 MONITOR	00816396020320
3303-38-15	MODEL 7600 MONITOR	00816396020337
3303-40-15	MODEL 7600 MONITOR	00816396020351
3303-41-15	MODEL 7600 MONITOR	00816396020368
3303-42-15	MODEL 7600 MONITOR	00816396020375
3303-44-15	MODEL 7600 MONITOR	00816396022232
3303-45-15	MODEL 7600 MONITOR	00816396022249
3303-46-15	MODEL 7600 MONITOR	00816396022454
3303-50-15	MODEL 7600 MONITOR	00816396022959
3303-52-15	MODEL 7600 MONITOR	00816396023192
7600EP Cardiac Trigger Monitor plus Accessory Kit		

Variant's Part Number	Description	UDI-DI
3303-47-15	MODEL 7600EP MONITOR	00816396022898
3303-48-15	MODEL 7600EP MONITOR	00816396022904
3303-49-15	MODEL 7600EP MONITOR	00816396022928
3303-51-15	MODEL 7600EP MONITOR	00816396021495
3303-53-15	MODEL 7600EP MONITOR	00816396023215
7800 Cardiac Trigger Monitor plus Accessory Kit		
3304-00-15	MODEL 7800 MONITOR	00816396020412
3304-01-15	MODEL 7800 MONITOR	00816396020429
3304-02-15	MODEL 7800 MONITOR	00816396020436
3304-03-15	MODEL 7800 MONITOR	00816396020443
3304-05-15	MODEL 7800 MONITOR	00816396020467
3304-06-15	MODEL 7800 MONITOR	00816396020474
3304-07-15	MODEL 7800 MONITOR	00816396020481
3304-08-15	MODEL 7800 MONITOR	00816396020498
3304-10-15	MODEL 7800 MONITOR	00816396020511
3304-11-15	MODEL 7800 MONITOR	00816396020528
3304-12-15	MODEL 7800 MONITOR	00816396020535
3304-14-15	MODEL 7800 MONITOR	00816396020559
3304-15-15	MODEL 7800 MONITOR	00816396020566
3304-16-15	MODEL 7800 MONITOR	00816396020573
3304-17-15	MODEL 7800 MONITOR	00816396020580
3304-18-15	MODEL 7800 MONITOR	00816396020597
3304-19-15	MODEL 7800 MONITOR	00816396020603
3304-20-15	MODEL 7800 MONITOR	00816396020610
3304-21-15	MODEL 7800 MONITOR	00816396020627
3304-23-15	MODEL 7800 MONITOR	00816396020641
3304-24-15	MODEL 7800 MONITOR	00816396020658
3304-25-15	MODEL 7800 MONITOR	00816396020665
3304-26-15	MODEL 7800 MONITOR	00816396020672
3304-27-15	MODEL 7800 MONITOR	00816396020689
3304-28-15	MODEL 7800 MONITOR	00816396020696
3304-29-15	MODEL 7800 MONITOR	00816396020702
3304-30-15	MODEL 7800 MONITOR	00816396020719
3304-31-15	MODEL 7800 MONITOR	00816396020726
3304-32-15	MODEL 7800 MONITOR	00816396022201
7810 Cardiac Trigger Monitor plus Accessory Kit		
3565-00-15	MODEL 7810 MONITOR	00816396020733
3565-01-15	MODEL 7810 MONITOR	00816396021464
3565-02-15	MODEL 7810 MONITOR	00816396021501