

# Declaration of Conformity

**Manufacturer:** Ivy Biomedical Systems, Inc.  
11 Business Park Drive  
Branford, CT 06405  
USA

**Authorized Representative:** Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands  
Tel: (31) (0) 70 345-8570

**Type of Equipment:** Physiological Monitors

**Models:** 7600, 7700, 7800 and 7810

We, Ivy Biomedical Systems, Inc., declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**Classification:** IIb **According to rule No.** 10

**Conformity Assessment Procedure:** Annex II excluding section 4

**Notified Body:** Intertek SEMKO AB **Notified Body No.** 0413

**Place of Issue:** Branford, CT

**Date of Issue:** 12 July 2021

**Name of Person Signing:** Felicia Piel

**Function of the Person Signing:** VP, Quality Assurance/Regulatory Affairs

**Signed On Behalf Of:** Ivy Biomedical Systems, Inc.

**Signature:**



# RoHS Directive

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This Declaration of Conformity is issued under the sole responsibility of 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.

**References to the relevant harmonised standards used:** EN IEC 63000:2018

**References to the technical specifications used:** N/A

**Additional information:** N/A

# EMC Directive (2014/30/EU)

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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 harmonisation legislation.

**Harmonised standards used:** N/A

**Conformity Assessment Procedure Performed:** Annex II of the Directive

**Certificates Issued:** N/A