

Declaration of Conformity

Manufacturer: Infinium Medical, Inc.
12151 62nd Street North # 5
Largo, Florida 33773 USA

EU Representative: Obelis S.A
Bd Général Wahis, 53
B-1030 Brussels
Belgium

Product: Patient Monitor

Product Models: OMNI, OMNI K, OMNI II, OMNI IIK, OMNI III, OMNI Express, CLEO

Classification: Class IIb, Rule 10 according to Annex IX of MDD 93/42/EEC

Assessment Procedure: Annex II – Annex IX

Standards Applied: ISO 13485:2012; EN ISO 14971:2012; ISO 15223-1:2016; IEC 60601- 1:2014; IEC 60601-1-2:2014; IEC 60601-1-6:2010; IEC 60601-1-8:2012; IEC 60601-2-27:2011; IEC 60601-2-34:2011; IEC 60601-2-49:2011; IEC 62304:2006; IEC 62366-1:2015; ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2009; IEC 80601-2-30:2009+AMD1:2013; ISO 80601-2-56:2009; ISO 80601-2-61:2011; EN 1041:2008+A1:2013

Notified Body: Kiwa Certification Services, Inc.
ITOSB 9. Cadde No: 15 Tepeören Tuzla
İstanbul – Türkiye

Product Marking: **CE**

The above product (s) complies with Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

I, the undersigned, declare on the basis of the above information that the products described above are in compliance with the requirements of Directive 93/42/EEC as indicated. This declaration hereby authorizes the CE Mark to be a fixed to the above-mentioned product(s).

Signature:


George Anello
Director of Quality Assurance &
Regulatory Affairs



Date: 01/11/2019

