IRADIMED CORPORATION

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DECLARATION OF CONFORMITY

The object of this declaration is in conformity with the following EU Council Directive:

- MDD 93/42/EEC concerning medical devices as amended by 2007/47/EC, including the requirements of Annex I

Product Name: 3880 MRI Patient Monitoring System

Product Model Numbers: 3880 MRI Patient Monitor (configurations 1-4)
3881 MRI Wireless ECG e-POD
3882 MRI Wireless SpO2 o-POD

Product Options: 3883 MRI Wireless IBP ip-POD (configurations 1-3)
3885T MRI Remote Tablet Display
3885B Base Station
3886 Multi-Gas Unit (configurations 3886 and 3886-1)

Product Accessories: Listed by the manufacturer in product accompanying documentation, Operation Manual REF 1200

Control Indicator: All devices shipped on or after the Date of Issue: December 12, 2019

Device Classification: IIb, per Annex IX, Rule 10 of 93/42/EEC

Global Medical Device Nomenclature Code: 61161, MRI Patient Physiologic Monitoring System

Manufacturer: Iradimed Corporation, 1025 Willa Springs Drive, Winter Springs, FL 32708 USA, www.iradimed.com

Authorized EU Representative: Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany, www.mdssar.com

Notified Body (NB): Ente Certificazione Macchine (ECM) SRL, Via Ca' Bella, 243/A - loc. Castello di Serravalle, 40053 Valsamoggia (BO), Italy, www.entecerma.it (CE Notified Body Identification Number: 1282)

Conformity Assessment Route: The notified body identified, ECM, performed an assessment per MDD 93/42/EEC Annex II, excluding Clause 4 and issued EC Certificate No. ECM19MDD012

Additional Information: The product has been tested in the fully optioned system as described in the manufacturer's accompanying documentation. Additionally, the accessories listed in the accompanying documentation have been tested and found to be compatible with the product. All supporting documentation is retained under the premises of the manufacturer. The product is compliant with the relevant harmonized standards as listed below.

Harmonized Standards to which Conformity is Declared: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-2-27, IEC 80601-2-30, IEC 60601-2-34, IEC 60601-2-49, ISO 80601-2-55, ISO 80601-2-56, ISO 80601-2-61, ISO10993, IEC 62366, IEC 62133, IEC 62304, IEC 10993 ISO, 13485, ISO 14971, ISO 15223

We, Iradimed Corporation, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices, as amended by Directive 2007/47/EC.

Place of Issue: Iradimed Corporation ,Winter Springs, FL, USA

Date of Issue: December 12, 2019

Signature: Francis X. Casey

Francis X. Casey
Vice-President, Q.A. & Regulatory Affairs