IRadimed CORPORATION
ADVANCED TECHNOLOGIES IN MR FLUID MANAGEMENT

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DECLARATION OF CONFORMITY

Application of Council Directive(s) Medical Device Directive 93/42/EC

Regulation(s) to which Conformity is Declared LVFS 2003:11

Standard(s) to which Conformity is Declared IEC 60601-1, ISO 9919

Manufacturer's Name Iradimed Corporation

Manufacturer's Address 7457 Aloma Ave., Winter Park, FL 32792 USA

Importer's Name Refer to accompanying Packing Slip

Importer's Address Refer to accompanying Packing Slip

Type of Equipment MRIdium 2460 Pulse Oximeter System and accessories

Model No(s). 2460 Series monitors and 1070 Series sensors

Serial No(s). Refer to accompanying Packing Slip

Year of Manufacture Refer to accompanying Packing Slip

Certification Method(s) Annex II

Equipment Class Class IIa and IIb

MDD Conformity Assessed By Semko (0413)

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s), Regulation(s) and/or Standard(s).

Place Winter Park, FL

Date January 4, 2013

Francis Casey
(Signature)

Francis Casey
(Full Name)

Regulatory Affairs
(Position)