DECLARATION OF CONFORMITY


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

Standard(s) to which Conformity is Declared ______ IEC 60601-1, IEC 60601-2-24, 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 ______ MRIedium 3860 Infusion Pump System and accessories ______

Model No(s). ______ 3860 Series and 1000 Series ______

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 ______

(Signature) ______ Francis Casey ______

(Full Name) ______ Regulatory Affairs ______

(Position) ______