IRADIMED CORPORATION

1025 Willa Springs Drive
Winter Springs, FL 32708
PH: 407-677-8022
FX: 407-677-5037

DECLARATION OF CONFORMITY

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

Regulation(s) to which Conformity is Declared: Medical Device Directive 93/42/EC

Standard(s) to which Conformity is Declared: IEC 60601-1, IEC 60601-2-24, ISO 80601-2-61

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

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

Importer's Name: Refer to accompanying Packing Slip

Importer's Address: Refer to accompanying Packing Slip

Type of Equipment: MRIdium 3860 Infusion Pump System and accessories

Model No(s).: 3860+/3860 Pump, 3861 Channel B SideCar, and 3865 Remote
1000 Series Infusion Sets, Type 1056, 1057 and 1058

Lot/Serial No(s).: Refer to accompanying Packing Slip

Year of Manufacture: Refer to accompanying Packing Slip

Certification Method(s): Annex II, EC Marking Certificates No. 1434-MDD-408/2019
and 1434-MDD-409/2019

Equipment Class(es): Class IIa and IIb

MDD Conformity Assessed By: Polish Center for Testing and Certification (1434)

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

Place Winter Springs, FL

Date December 3, 2019

Francis Casey
(Signature)

Francis Casey
(Full Name)

Vice-President, Q.A. & Regulatory Affairs
(Position)