MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of **Council Directives 93/42/EEC of 14th June 1993, concerning medical devices**;

Company Headquarters: Issuer of Declaration	ICU Medical, Inc.		
Business Address:	600 North Field Drive, Lake Forest, Illinois 60045, USA		
EU Authorized Representative:	ICU Medical BV Hofspoor 3 3994 VZ Houten The Netherlands		
Manufacturing Sites(s):	ICU Medical Costa Rica Ltd 1 Km Noreste del Centro Comercial Real Cariari Zona Franca Global PK La Aurora de Heredia Costa Rica		
Medical Devices: Identification of object of the declaration:	**List Number:**	**Product Name:**	**GMDN code:**
	30010	Plum 360™ Infusion Pump	13215
MDD Classification:	Class: IIb	Rule 11, according to Annex IX of the MDD	

Statement of Conformity:

We, ICU Medical, Inc., declare that the products described herein comply with the Essential Requirements and applicable provisions of:

Council Directive 93/42/EEC of 14th June 1993, concerning medical devices,

The medical devices represented by this declaration are certified according to Annex II of the Council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

93/42/EEC Annex II (excluding section 4) EC Certification: **Design and manufacture of Infusion Pumps excluding accessories and administration sets**
EC Certificate Number: **CE 674103**

Issued by: BSI Group The Netherlands B.V. (Notified Body Number 2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of **Council Directives 93/42/EEC of 14th June 1993, concerning medical devices**;

Standards applied:

Standard reference	Standard title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007/AC:2010/ A11:2017	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-2-24:1998 IEC 60601-2-24:2012	Medical electrical equipment -- Part 2-24: Particular requirements for the safety of infusion pumps and controllers
EN 1041:2008 /A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of **Council Directive 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment**

<table>
<tr><td>Company Headquarters:
Issuer of Declaration</td><td colspan="3">ICU Medical, Inc.</td></tr>
<tr><td>Business Address:</td><td colspan="3">600 N. Field Drive,
Lake Forest,
Illinois 60045, USA</td></tr>
<tr><td>EU Authorized Representative:</td><td colspan="3">ICU Medical B.V.
Hofspoor 3, 3994 VZ Houten,
The Netherlands</td></tr>
<tr><td rowspan="2">Products:
Identification of object of the declaration:</td><td>Model Number:
Plum 360
30010</td><td>Product Name:
Plum 360™ Infusion Pump</td><td>GMDN code:
13215</td></tr>
<tr><td colspan="2">Radio Equipment
Wireless Local Area Network</td><td>ACCESSORIES
None</td></tr>
<tr><td>Notified Body (NB)</td><td colspan="3">Siemic Laboratories, 775 Montague Expressway, Milpitas, CA 95035</td></tr>
<tr><td>NB Identification No.</td><td colspan="3">2200</td></tr>
<tr><td>EU-Type Examination certificate</td><td colspan="3">RE-17053001</td></tr>
</table>

Statement of Conformity:

We, ICU Medical, Inc., declare that the products described herein comply with the Essential Requirements and applicable provisions of:

2014/53/EU of 16th April 2014, the Radio Equipment Directive

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of **Council Directive RED Directive 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment**

Standards applied:

Standard reference	Standard title
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields(0 Hz to 300 GHz)
EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU;
EN 301 893 V2.1.0	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17 V3.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems;
EN 61000-4-2:2009	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test
EN 61000-4-3:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-4:2012	Electromagnetic compatibility (EMC). Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-5:2014	Electromagnetic Compatibility (EMC) – Testing and Measurement Techniques – Surge Immunity Test
EN 61000-4-6:2014	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
EN 61000-3-2:2014	Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 55032:2012+AC:2013	Electromagnetic compatibility of multimedia equipment - Emission requirements

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of **Council Directive 2011/65/EU of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Recast)**

Company Headquarters: Issuer of Declaration	ICU Medical, Inc.		
Business Address:	600 N. Field Drive, Lake Forest, Illinois 60045, USA		
EU Authorized Representative:	ICU Medical BV Hofspoor 3 3994 VZ Houten The Netherlands		
Products: Identification of object of the declaration:	**List Number:**	**Product Name:**	**GMDN code:**
	30010 (comprising of 30011 or 30012)	Plum 360™ Infusion Pump	13215

Statement of Conformity

We, ICU Medical Inc, also declare that the electrical and electronic equipment (EEE) described herein comply with the applicable provisions of:

2011/65/EU of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Recast)

Standards applied:

Standard reference	Standard title
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number: Plum 360™ Infusion Pump 22973519665

This is a declaration made under the sole responsibility of ICU Medical in accordance with the requirements of Council Directives:

1) **2012/19/EU of 4th July 2012 on waste electrical and electronic equipment (WEEE);**

2) **2006/66/EC of 6th September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC**

Company Headquarters: Issuer of Declaration	ICU Medical, Inc.		
Business Address:	600 N. Field Drive, Lake Forest, Illinois 60045, USA		
EU Authorized Representative:	ICU Medical BV Hofspoor 3 3994 VZ Houten The Netherlands		
Products: Identification of object of the declaration:	**List Number:**	**Product Name:**	**GMDN code:**
	30010 (comprising of 30011 or 30012)	Plum 360™ Infusion Pump	13215

Statement of Conformity

We, ICU Medical Inc., also declare that the products described herein comply with the applicable provisions of:

2012/19/EU of 4th July 2012 on waste electrical and electronic equipment (WEEE);

2006/66/EC of 6th September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

Authorised Signatories:

Name: Yuliya Matlin
Dept: Global Regulatory Affairs

Signature 04/03/2019 Date

Name: Robert Cousineau
Dept: Research and Development

Signature 03-29-2019 Date

Place of Issue:	Lake Forest, Illinois