

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number CE 674107 / Administration Sets
(Sterile Intravenous & Blood Transfusions and Non-Sterile Adult / Paediatric Enteral Feeding Kits)

This is a declaration made in accordance with the requirements of the European Council Directive 93/42/EEC of 14th June 1993, concerning medical devices (MDD)

Manufacturer	ICU Medical, Inc.	
Business Address:	600 North Field Drive, Lake Forest, Illinois, 60045, USA	
EU Authorized Representative:	ICU Medical B.V. Hofspoor 3, 3994 VZ Houten The Netherlands	
Medical Devices: Identification of object of the declaration:	List numbers and descriptions are included in Attachment A of this document	
MDD Classification:	Class: IIa	Rule II, according to Annex IX of the MDD

Statement of Conformity:

We ICU Medical, Inc. solely declare that the above products, described herein, complies with the Essential Requirements and applicable provisions of the Council Directive 93/42/EEC of 14th June 1993, concerning medical devices and the transitional provisions of (EU) 2017/745 Article 120(3).

This declaration is based on:

Devices are certified according to Annex V of the council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

EC Certificate: CE 674107

Product Scope: Manufacture of Administration sets used for; Sterile Intravenous & Blood transfusions and Non-Sterile Adult / Paediatric Enteral Feeding Kits.

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

Notified Body Number: 2797

Authorised Signatories:

Issuers Name: Nichelle Cato
Dept: Global Device Regulatory Affairs

Nichelle Cato 06 June 2023
Signature Date

Place of Issue:	San Clemente, California	Date of issue:	06 June 2023
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Standards Applied

Standard Reference	Standard Title
EN ISO 13485:2016+AC:2018	Medical devices - quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	Application of risk management to medical devices
EN 20594-1: 1993/A1:1997 (ISO 594-1: 1996)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1 General Requirements
EN 1707:1996 (ISO 594-2:1998)	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Lock Fittings
EN ISO 10993-1 2020	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
EN ISO 10993-4: 2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
EN ISO 10993-11: 2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12: 2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17: 2017	Biological evaluation of medical devices – Part 17: Establishment of allowable limits of leachable substances
EN ISO 10993-18: 2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 8536-4: 2010/ Amd 1, 2013; 2020	Infusion Equipment for medical use – Part 4: Infusion sets for single use, gravity feed
EN ISO 8536-5: 2004	Infusion equipment for medical use – Part 5: Burette infusion sets for single use, gravity feed
EN ISO 8536-8: 2015	Infusion equipment for medical use Part 8: Infusion equipment for use with pressure infusion apparatus
EN ISO 8536-11: 2015	Infusion equipment for medical use - Part 11: Infusion filters for use with pressure infusion equipment
EN ISO 8536-12: 2020	Infusion equipment for medical use-Part 12: Check valves for single use
EN ISO 1135-4: 2015	Transfusion equipment for medical use – Part 4: Transfusion sets for single use
EN ISO 11607-1: 2020	Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11137-1:2015	Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2: 2015	Sterilization of Health Care Products – Radiation –Part 2: Establishing the sterilization dose.
EN 556-1:2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 20417: 2021	Medical Devices – Information to be provided by the manufacturer
EN 62366-1: 2015+AC:2016+A1:2020	Medical devices - Application of usability engineering to medical devices
EN ISO 15223-1: 2016	Symbols to be used with medical device labels, labelling and information to be supplied Part 1 – General requirements
EN 15986: 2011	Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates
EN ISO 11737-1: 2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2: 2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

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EN ISO 80369-1: 2018	Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 1: General Requirements.
EN ISO 80369-3:2016	Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 3: Connectors for enteral applications
EN ISO 80369-6:2016	Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 6: Connectors for neuraxial application
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
EN 60601-1: 2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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Attachment A – Product List

Sub-Family	List Number	Description	GMDN
Plum	12193	Primary PLUM™ Set 2 CLAVE™ Multiport Connector, Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE Secondary Port, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Secure Lock 213 cm /18 mL	35833
Plum	12194	Primary PLUM™ Set 2 CLAVE™ Multiport Connector, Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE Secondary Port, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 213 cm /18 mL	35833
Plum	12195	Primary PLUM™ Set 4 CLAVE™ Multiport Connector, Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE Secondary Port, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Secure Lock 216 cm /19 mL	35833
Plum	12196	Primary PLUM™ Set 4 CLAVE™ Multiport Connector, Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE Secondary Port, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 216 cm / 19 mL	35833
Plum (Burette)	12564	Primary PLUM™ 150 mL Burette Set CLAVE™ Additive Port, 15 Micron Filter in Sight Chamber, 2 CLAVE Y-Sites, Secure Lock 290 cm / 19 mL Retrograde Volume is Approximately: 8.3 mL	35833
Plum	14000	Primary PLUM™ Set, 15 Micron Filter in Sight Chamber, Prepierced Y-Site, Secure Lock, 272 cm / 19 mL	35833
Plum	14001	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, CLAVE Y-Site, Secure Lock 272 cm / 19 mL	35833
Plum	14003	Primary PLUM™ 150 mL Burette Set Prepierced Additive Port, 15 Micron Filter in Sight Chamber, Prepierced Secondary Port, 2 Prepierced Y-Sites, Secure Lock 290 cm/ 19.4mL Retrograde Volume is approximately: 7.9 mL	35833
Plum	14006	PRIMARY PLUMSET™, 15 Micron Filter in Sight Chamber, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing Secure Lock 272 cm / 12 cm	35833
Plum	14007	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock 272 cm / 12 mL	35833
Plum	14009	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock 272 cm / 15 mL	35833
Plum	14011	Primary PLUM™ MICRODRIP™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock 272 cm / 12 mL	35833
Plum	14012	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, Secure Lock 225 cm / 17 mL	35833
Plum	14014	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, 0.2 Micron Filter, Polyethylene Lined Tubing, Secure Lock 225 cm / 20 mL	35833
Plum	14015	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 272 cm / 23 mL	35833
Plum	14017	Primary PLUM™ MICRODRIP™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 272 cm / 20 mL	35833
Plum	14018	Primary Plum™ Set, 15 Micron Filter in Sight Chamber, Single Channel Cassette Secure Lock, 272 cm / 19 mL	35833
Plum	14019	Primary Plum™ Set, 15 Micron Filter in Sight Chamber, Single Channel Cassette CLAVE™ Y-Site, Secure Lock, 272 cm / 19 mL	35833
Plum	14022	Primary PLUM™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, 1.2 Micron Filter, CLAVE Y-Site, Secure Lock 264 cm / 22 mL	35833
Plum	14024	Primary PLUM™ MICRODRIP™ Set 15 Micron Filter in Sight Chamber, CLAVE™ Secondary Port, CLAVE Y-Site, Distal Microbore Tubing, Secure Lock 262 cm / 12.7 mL	35833
Plum (Blood)	14210	Primary PLUM™ Blood Set 100 mL Burette with Prepierced Additive Port, 170 Micron Filter, Prepierced Secondary Port, Non-Vented, Secure Lock 267 cm / 22 mL	38569

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Plum (Blood)	14211	Primary PLUM™ Blood Set 200 Micron Filter, Prepierced Secondary Port, Secure Lock 279 cm / 52 mL	38569
Plum (Blood)	14212	Primary PLUM™ Y-Type Blood Set 200 Micron Filter, CLAVE™ Secondary Port, Non-Vented, Secure Lock 279 cm / 49 mL	38569
Plum	14238	Microbore Conversion PLUM™ Set Prepierced Y-Site, Secure Lock 188 cm / 7.1 mL	35833
Plum	14240	Primary PLUM™ Set Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE™ Secondary Port, CLAVE Y-Site, Secure Lock 264 cm / 20 mL	35833
Plum	14241	Primary PLUM™ Set Ball Check Valve in Sight Chamber, 15 Micron Filter, CLAVE™ Secondary Port, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, CLAVE Y-Site, Secure Lock 264 cm / 12 mL	35833
Plum (Blood)	19673	Primary Plum™ Blood Set, 200 Micron Filter, CLAVE™ Secondary Port, Non-Vented, Secure Lock 259 cm / 51 mL	38569
Plum (Enteral)	14025	Primary PLUM™ Enteral Set Integral Container, Enteral Catheter Adapter 264 cm / 16 mL	64461
Plum (Enteral)	14259	Primary PLUM™ Enteral Set 40 mm Screw Cap, Enteral Catheter Adapter 249 cm / 18 mL	64461
Gravity (Extension)	04522	Extension Set 2 Prepierced Y-Sites, Secure Lock 84 cm / 5 mL	12170
Gravity (Secondary)	14028	SECONDARY SET 15 Micron Filter in Sight Chamber 86 cm / 6 mL	58977
Gravity (Blood)	14202	Primary Blood Set 100 mL Burette with Float Valve, Prepierced Additive Port, 170 Micron Filter, Non-Vented, Secure Lock 178 cm / 13 mL	38569
Gravity (Blood)	14203	Primary Blood Set 200 Micron Filter, Secure Lock 203 cm / 47 mL	38569
Gravity (Blood)	14204	Primary Blood Set 200 Micron Filter, Cylinder Pump, Secure Lock 203 cm / 95 mL	38569
Gravity (Blood)	14205	Primary Blood Set 200 Micron Filter, Convertible Pin and Non-Vented Pin, Secure Lock 203 cm / 47 mL	38569
Gravity (Blood)	14206	Primary Y-Type Blood Set 200 Micron Filter, Cylinder Pump, Convertible Pin and Non-Vented Pin, Secure Lock 203 cm / 94 mL	38569
Gravity	14225	Primary MICRODRIP™ Set 15 Micron Filter in Sight Chamber, Prepierced Y-Site, Secure Lock 203 cm/13mL	58977
Gravity	14226	Primary Set 15 Micron Filter in Sight Chamber, Prepierced Y-Site, Secure Lock 203 cm / 13 mL	58977
Gravity (Burette)	14236	Primary MICRODRIP™ 150 mL Burette Set with Float Valve, Prepierced Additive Port, 15 Micron Filter in Sight Chamber, Prepierced Y-Site, Secure Lock 198 cm / 13 mL	58977
Gravity (Burette)	19208	150 mL Burette Set with Float Valve, CLAVE™ Injection Site, MICRODRIP, 15 Micron Filter in Sight Chamber, CLAVE Y-Site 198 cm / 16 mL	58977
Sapphire	16324	SAPPHIRE™ Primary 1.2 Micron Filter Set Non-Vented, CLAVE™ Y-Site 289 cm / 18 mL	35833
Sapphire	16327	SAPPHIRE™ Primary Set 15 Micron Filter in Sight Chamber, CLAVE™ Y-Site 283 cm / 17 mL	35833
Sapphire	16328	SAPPHIRE™ Primary 1.2 Micron Filter Set 15 Micron Filter in Sight Chamber, Prepierced Y-Site 284 cm / 19 mL	35833
Sapphire	16332	SAPPHIRE™ Primary 0.2 Micron Filter Set 15 Micron Filter in Sight Chamber, CLAVE™ Y-Site 284 cm / 19 mL	35833
Sapphire	16335	SAPPHIRE™ Primary 1.2 Micron Filter Set Non-Vented, Microbore 311cm / 8.4 mL	35833
Sapphire	16336	SAPPHIRE™ Polyethylene-Lined Light Resistant Primary Set 15 Micron Filter in Sight Chamber, CLAVE Y-Site 281 cm / 17 mL	35833
Sapphire (Epidural)	16339	SAPPHIRE™ Epidural Set Non-Vented, Yellow-Striped Microbore 298 cm / 5.4 mL	35833
Sapphire	16340	SAPPHIRE™ Primary Piggyback Set 15 Micron Filter in Sight Chamber, 2 CLAVE™ Y-Sites 281 cm / 17 mL	35833
Sapphire	16345	SAPPHIRE™ Primary 0.2 Micron Filter Set Non-Vented, Microbore 293 cm / 8.1 mL	35833

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Sapphire	16346	SAPPHIRE™ Primary Set Microbore 298cm / 5.4 mL	35833
Sapphire (Blood)	16347	SAPPHIRE™ Y-Type Blood Set 200 Micron Blood Filter, CLAVE™ Y-Site 281 cm / 53 mL	38569
Sapphire	16350	SAPPHIRE™ Female Luer Lock Primary Set, Microbore, CLAVE Y-Site 289 cm / 5.3 mL	35833
Sapphire	16362	SAPPHIRE™ Primary 0.2 Micron Filter Set, Microbore, Clave Y-Site, 299cm	35833
Sapphire (Epidural)	16363	SAPPHIRE™ Epidural Set Yellow-Striped Microbore, 0.2 Micron Filter 301 cm / 8.3 mL	35833
Sapphire (Extension)	16371	SAPPHIRE™ Non-Vented PCA Set KVO Y-Extension, Microbore 301 cm / 6.4 mL	35833
Sapphire (Extension)	16372	SAPPHIRE™ Non-Vented PCA Set KVO Y-Extension, Microbore, PAV 293 cm / 6.4 mL	35833
Sapphire (Epidural)	16374	SAPPHIRE™ Epidural Set Non-Vented, Yellow-Striped Microbore, PAV 300 cm / 5.6 mL	35833
Sapphire	16381	SAPPHIRE™ Primary Set Non-Vented, Microbore, PAV 300 cm / 5.6 mL	35833
Sapphire (Blood)	16432	SAPPHIRE™ Blood Set 200 Micron Blood Filter 287 cm / 49 mL	38569
Sapphire (Epidural)	24009	SAPPHIRE™ Epidural Set with NRFit™ Connector, Non-Vented, Yellow-Striped Microbore 298 cm/5.4 mL	35833
Sapphire (Epidural)	24011	SAPPHIRE™ Epidural Set with NRFit™ Connector, Yellow-Striped Microbore, 0.2 Micron Filter 301 cm/8.3 mL	35833
Sapphire (Epidural)	24016	SAPPHIRE™ Epidural Set with NRFit™ Connector Non-Vented, Yellow-Striped Microbore, PAV 300 cm/5.6 mL	35833
Sapphire H100	16406	SAPPHIRE™ H100 Primary Set, 15 Micron Filter in Sight Chamber 280 cm / 16 mL	35833
Sapphire H100	16407	SAPPHIRE™ H100 Primary Set, 15 Micron Filter in Sight Chamber, Prepierced Y-Site, Secure Lock 280 cm / 17 mL	35833
Sapphire H100	16408	SAPPHIRE™ H100 Primary Set, Sight Chamber With Ball Check Valve, 15 Micron Filter, Clave™ Y-Site 280 cm / 17 mL	35833
Sapphire H100	16409	SAPPHIRE™ H100 Primary Set, 15 Micron Filter in Sight Chamber, Polyethylene Lined Light Resistant Tubing 280 cm / 16 mL	35833
Sapphire H100	16410	SAPPHIRE™ H100 Primary Set, Sight Chamber with Ball Check Valve, 15 Micron Filter, Clave™ Y-Site Polyethylene Lined Light Resistant Tubing 280 cm / 17 mL	35833
Sapphire H100	16416	SAPPHIRE™ H100 Primary Set, 2 CLAVE™ Multiport Connector, Sight Chamber with Ball Check Valve, 15 Micron Filter, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing 300 cm / 18 mL	35833
Sapphire H100	16417	SAPPHIRE™ H100 Primary Set, 2 CLAVE™ Multiport Connector, Sight Chamber with Ball Check Valve, 15 Micron Filter, CLAVE Y-Site, Polyethylene Lined Tubing 300 cm / 18 mL	35833
Sapphire H100	16419	SAPPHIRE™ H100 Primary Set, 4 CLAVE™ Multiport Connector, Sight Chamber with Ball Check Valve, 15 Micron Filter, CLAVE Y-Site, Polyethylene Lined Tubing 300 cm / 18 mL	35833
Sapphire H100	16420	SAPPHIRE™ H100 Primary Set, 15 Micron Filter in Sight Chamber, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing 280 cm / 17 mL	35833

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REVISION HISTORY*

RA Note: This section is for internal use only. Remove this page(s) prior to external sharing of signed copy.

Rev No.	Change Description	Reason for Change	Date of Change
07	1. Add reference to MDR in statement of conformity 2. Add revision history page 3. Clarify product sub-family (i.e. blood sets) 4. Update GMDN code per sub-family 5. Updated standards list 6. Remove LN 16326	1. Clarification during transition to MDR 2. To track changes to EC DoC 3. For clarity 4. Align code with proper device intended use 5. Align with technical file list of applied standards 6. LN is domestic code	Per signature date
08	1. Add LN 16362	1. LN 16326 was incorrectly presented in 3March2021 revision DoC and thereby removed in Rev07 of DoC. The correct LN is 16362.	Per signature date
09	1.Add EN ISO 20417	1. Update to Standard	Per signature date