

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.1002 / Vial Adaptors

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:	951 Calle Amanecer, San Clemente, California 92673 USA	
EU Authorized Representative:	Medical Device Safety Service, GmbH (MDSS) Schiffgraben 41 D-30175 Hannover, Germany	
Medical Devices: Identification of object of the declaration:	List numbers and descriptions are included in Attachment A of this document	
MDD Classification:	Class: I sterile	Rule 2 (paragraph 2) according to Annex IX of the MDD
GMDN Code:	60539	

Statement of Conformity:

We ICU Medical, Inc. solely declare that the above products, described herein, comply 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 II, Section 3.2 of the council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

EC Certificate Number: 252.1002

Product Scope: Vial Adaptors

Notified Body: National Standards Authority of Ireland (NSAI)
1 Swift Square, Northwood, Santry,
Dublin 9, Ireland

Notified Body Number: 0050

Authorised Signatory:

Issuers Name: Sheila Antonio
Dept: Global Device Regulatory Affairs

06 Jan 2022
Signature Date

Place of Issue: San Clemente, California	Date of issue: 06 Jan 2022
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Standards Applied

Standard	Title	Version/ Edition <i>*non-harmonized</i>
EN ISO 13485	Medical devices - quality management systems – Requirements for regulatory purposes	2016
EN ISO 14971	Application of risk management to medical devices	2019
EN 20594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	1993/ A1:1997
EN ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications	2017*
EN ISO 8536-4	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed	2020*
EN ISO 8536-10	Infusion equipment for medical use -- Part 10: Accessories for fluid lines for single use with pressure infusion equipment	2015*
EN ISO 22413	Transfer sets for pharmaceutical preparations — Requirements and test methods	2013*
EN ISO 10993-1	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process	2009/ AC:2010
EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-7	Biological evaluation of medical devices — Part 7: Ethylene Oxide Residuals	2008/AC:2009
EN ISO 10993-10	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	2010*
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009
EN ISO 11607-1	Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2006
EN ISO 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical device	2007
EN ISO 11137-1	Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2006/ AC:2009; 2015
EN ISO 11137-2	Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose.	2009/ 2015
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001/AC: 2006
EN 1041	Information supplied by the Manufacturer of medical devices	2008
EN 62366	Medical devices - Application of usability engineering to medical devices	2008
EN ISO 15223-1	Symbols to be used with medical device labels, labelling and information to be supplied Part 1 – General requirements	2016
EN 15986	Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates	2011
EN ISO 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	2006/AC:2009
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2009

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Attachment A – Product List

List Number	Description
011-CH-51	Universal Vented Vial Spike w/ ChemoClave™
011-CH-51-10	Universal Vented Vial Spike w/ ChemoClave™, 10 units
011-CH-53	ChemoClave® Vented Vial Spike, 20mm – No Skirt
011-CH-62	ChemoClave™ Vial Spike, 13mm
011-CH-62-C	ChemoClave® Vial Spike (Cap without Cone), 13mm
011-CH-70	ChemoClave® Universal Vented Vial Spike
011-CH-70-5	ChemoClave™ Universal Vented Vial Spike, 5 Units
011-CH-70-10	ChemoClave™ Universal Vented Vial Spike, 10 Units
011-CH-70-15	ChemoClave® Universal Vented Vial Spike, 15 Units
011-CH-70S	ChemoClave® Vented Vial Spike, 20mm
011-CH-70S-10	ChemoClave® Vented Vial Spike, 20mm, 10 Units
011-CH-70S-20	ChemoClave® Vented Vial Spike, 20mm, 20 Units
011-CH-70S-5	ChemoClave® Vented Vial Spike, 20mm, 5 Units
011-CH-70SXL	ChemoClave® Vented Vial Spike, 32mm
011-CH-72	ChemoClave™ Vented Vial Spike, 13mm
011-CH-72-10	ChemoClave™ Vented Vial Spike, 13mm, 10 Units
011-CH-72-20	ChemoClave® Vented Vial Spike, 13mm, 20 Units
011-CH-72-25	ChemoClave® Vented Vial Spike, 13mm, 25 Units
011-CH-72-5	13mm Vented Vial Spike with Tritan, ChemoClave®, 5 units
011-CH-74	ChemoClave™ Universal Vented Vial Spike
011-CH-74-10	ChemoClave™ Universal Vented Vial Spike, 10 Units
011-CH-74-15	ChemoClave™ Universal Vented Vial Spike, 15 Units
011-CH-74S	ChemoClave™ Vented Vial Spike, 20mm
011-CH-74S-10	ChemoClave™ Vented Vial Spike, 20mm, 10 units
011-CH-80	ChemoClave® Closed Vial Spike
011-CH-80-5	ChemoClave® Vial Spike, 5 Units
011-CH-80S	ChemoClave® Vial Spike, 20mm
011-CH-80S-4	ChemoClave® Vial Spike, 20mm, 4 Units
011-CH-80SL	ChemoClave® Vial Spike, 28mm
011-CH-80SXL	ChemoClave® Vial Spike, 32mm
011-CH-82	ChemoClave® 13mm Closed Vial Spike
011-CL-50	ChemoLock™ Vial Spike
011-CL-51	Universal Vented Vial Spike, ChemoLock™
011-CL-51-25	ChemoLock™ Port w/Vented Vial Spike – 25 Units
011-CL-53	Spike with Bonded ChemoLock™ Port
011-CL-62	13mm Closed Vial Spike, ChemoLock™
011-CL-70	Locking Universal Vented Vial Spike, ChemoLock™
011-CL-70-10	ChemoLock™ Universal Vented Vial Spike, 10 units

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List Number	Description
011-CL-70S	ChemoLock™ Vented Vial Spike, 20mm
011-CL-70S-5	ChemoLock™ Vented Vial Spike, 20mm, 5 Units
011-CL-70S-10	ChemoLock™ Vented Vial Spike, 20mm, 10 units
011-CL-70S-20	ChemoLock™ Vented Vial Spike, 20mm, 20 Units
011-CL-70SL	ChemoLock™ Vented Vial Spike, 28mm
011-CL-70SXL	ChemoLock™ Vented Vial Spike, 32mm
011-CL-72	ChemoLock™ Vented Vial Spike, 13mm
011-CL-72-10	ChemoLock™ Vented Vial Spike, 13mm, 10 Units
011-CL-80	ChemoLock™ Closed Vial Spike
011-CL-80S	ChemoLock™ Vial Spike, 20mm
011-CL-80S-5	ChemoLock™ Vial Spike, 20mm, 5 Units
011-CL-80SL	ChemoLock™ Vial Spike, 28mm
011-CL-80SXL	ChemoLock™ Vial Spike, 32mm
011-CL-82	ChemoLock™ 13mm Closed Vial Spike
011-CS-35	Ampule Access Straw, Non-DEHP, Smallbore
011-CS-40	Single Dose Vial Access Spike
011-CS-50	CLAVE® Connector Multi-Dose Vial Access Spike
011-CS-50G	Clave™ (Glow Ring) Multi-Dose Vial Access Spike
011-CS-50GR	Clave™ (Green Ring) Multi-Dose Vial Access Spike
011-CS-50PR	Clave™ (Purple Ring) Multi-Dose Vial Access Spike
011-CS-50RR	Clave™ (Red Ring) Multi-Dose Vial Access Spike
011-CS-50YR	Clave™ (Yellow Ring) Multi-Dose Vial Access Spike
011-CS-51G	Dispensing Pin with 0.2 Micron Vent, Clave™ (Glow Ring)
011-CS-51RR	Dispensing Pin with 0.2 Micron Vent, Clave™ (Red Ring)
011-CS-55	CLAVE® Connector Multi-Dose Spike, Check Valve
011-CS-75	Vented Vial Spike, 20mm, Tritan
011-CV-100	CLAVE® Multidose Vial Access Cap
011-H2393	10 units Spike with Bonded CLAVE® Connector
011-H2421	25 units Spike with Bonded CLAVE® Connector
011-H2422	25 units of Dispensing Pin with 0.2 Micron Vent, CLAVE®
011-H2778	25 Units Universal Vial Spike w/CLAVE®
011-H2881	Single Dose Vial Spike
011-H2808	5 mL Vial Adapter w/Clave™, 25 Units
011-H2936	25 units Spike with Bonded CLAVE® Connector
011-H2937	25 Units of Dispensing Pin with 0.2 Micron Vent,CLAVE®
011-H3010	10 units of Dispensing Pin with 0.2 Micron Vent,CLAVE®
011-H3473	15 Units of CLAVE®, w/ Dispensing Pin with 0.2 Micron Vent
011-H3474	10 units of CLAVE® w/5 mL Vial Adapter
011-H3477	10 Units of CLAVE® w/Dispensing Pin with 0.2 Micron Vent
011-H3703	Locking Universal Vial Spike with Clave, 20 Units

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List Number	Description
011-PH-51	Universal Vented Vial Spike
011-PH-62	13mm Vial Spike
011-PH-70	Universal Vented Vial Spike
011-PH-70S	20mm Vented Vial Spike
011-PH-70SL	28mm Vented Vial Spike
011-PH-72	13mm Vented Vial Spike
034-CH-70	Punzón p/ vial c/ filtro y CLV
034-CH-70-15	Punzon Universal con filtro de venteo ChemoClave®, 15 Unidades
034-CH-70S	Punzon venteo para vial ChemoClave®, 20mm
034-CH-70SL	Punzon venteo para Vial ChemoClave®, 28mm
034-CH-70SXL	ChemoClave® Punzón Vial c/filtro, 32 mm
034-CH-72	Punzón 3onclave®, Tritán, 13m
034-CH-80	Punzón Universal conCLAVE® y camara
034-CH-80S	Punzon para Vial ChemoClave®, 20mm
034-CH-80SL	Punzon para Vial ChemoClave®, 28mm
034-CH-80SXL	ChemoClave® Punzón Vial, 32 mm
034-CH-82	ChemoClave™, Punzón Vial cerrado 13 mm
034-CL-51	ChemoLock™, Punzón Univ. Vial c/ Filtro
034-CL-70	ChemoLock™, Punzón Univ. Vial c/ Filtro, fijación
034-CL-72	ChemoLock™, Punzón Vial Tritán c/ Filtro, 13mm
034-CL-80	ChemoLock™, Punzón Vial cerrado
034-CL-80S	ChemoLock® Punzón para vial, 20mm
034-CL-80SL	ChemoLock® Punzón para vial, 28mm
034-CL-80SXL	ChemoLock® Punzón para vial, 32mm
034-CL-82	ChemoLock™, Punzón Vial cerrado 13 mm
034-CS-51	Punzon con filtro venteo, 0,2 Micras, Clave™
034-CS-52	Punzon para vial con filtro de 5 micras, Clave®, 0,38 ml aprox
034-CS-53	Punzon con conector Clave®
039-CH-70S	ChemoClave® Perforatore per flaconi con filtro aria, 20mm
039-CH-72	ChemoClave® Perforatore per flaconi con filtro aria, 13mm
CH-10	ChemoClave™ Bag Spike
CH-100	ChemoClave® Vial Spike, 20mm
CH-41	Vial Adapter w/.22 Vent, No Skirt
CH-50	CLAVE® Connector Multi-Dose Vial Access Spike
CH-51	CLAVE® Vial Adapter w/.22 Vent, No Skirt
CH-51-10	CLAVE® Vial Adapter w/.22 Vent, No Skirt, 10 Units
CH-61	50 mL Vial Adapter w/.22 Micron Vent and CLAVE®
CH-62	5 mL Vial Adapter w/CLAVE®
CH-63	Vial Adapter, 10-50 mL w/.22 Micron Vent, 5 Micron Fluid Filter, CLAVE®

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List Number	Description
CH-70	Universal Vial Spike w/Clave
CH-70-10	Locking Universal Vented Vial Spike,CLAVE®, 10 Units
CH-70-1N	Universal Spike mitCLAVE®
CH-70-5	Locking Universal Vented Vial Spike w/Clave®, 5 Units
CH-70-5E	Universal Spike mitCLAVE®
CH-70S	Universal Vial Access w/Skirt and Large Filter, CLAVE®
CH-70S-5	ChemoClave™ Vented Vial Spike, 20mm, 5 units
CH-70SL	ChemoClave® Vented Vial Spike, 28mm
CH-72	13mm Vented Vial Spike with Tritan,CLAVE®
CH-73	14mm Vented Vial Spike with Tritan
CH-74	Locking Universal Vented Vial Spike, CLAVE®
CH-74-10	Locking Universal Vented Vial Spike, CLAVE®, 10 Units
CH-74-15	15 Units Locking Universal Vented Vial Spike w/Clave®
CH-74S	Universal Vial Access w/Skirt and Large Filter,CLAVE®
CH-74S-10	ChemoClave® Vented Vial Spike, 20mm, 10 units
CH-77YR	Genie® 20mm Closed Vial Spike,CLAVE® (Yellow Ring)
CH-80-3	ChemoClave® Closed Vial Spike, 3 Units
CH-80S	ChemoClave™ Closed Vial Spike
CH-82	ChemoClave™ 13mm Closed Vial Spike
CS-50	Clave™ Multi-Dose Vial Access Spike
CS-51	Dispensing Pin with 0.2 Micron Vent,CLAVE® /CLAVE® Connector con Mini Perforatore
CS-52	Chemo Dispensing Pin with 5 µ Filter and 0.2 µ Vent,CLAVE®
CS-53	5cm (2") Spike with Bonded CLAVE® Connector
SN1204C	Adapter Spike Onko mit Clave™
OPP3000	5 ml Vial Adapter w/Needlefree Connector

END OF PRODUCT LIST

REVISION HISTORY*

**RA Note: This section is for internal use only.
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Rev No.	Change Description	Reason for Change	Date of Change
1	- Added revision history page - Added GMDN code column to product list - Removed the following from the product list: - CH-62-NS, ChemoClave® Vial Spike, 13mm, non-sterile - CH-71-NS, UNIVERSAL VIAL SPIKE, NON-STERILE BULK - AH-72, ChemoClave® Vented Vial Spike, 13mm 011-CH-70-NS, ChemoClave® Universal Vented Vial Spike, Bulk Non-Sterile 011-CH-74-5, Locking Universal Vented Vial Spike, Clave®, 5 Units 01C-CH-51, Universal Vented Vial Spike, CLAVE® 01C-CH-61, 50 mL Vial Adapter w/.22 Micron Vent and CLAVE® 01C-CH-70, Universal Vial Spike w/Clave® 01C-CH-71, Locking Universal Vented Vial Spike 01C-CH-77, Genie w/Closed Vial Access Device, CLAVE® 052-NU-70, Universal vented vial spike, Nunitiv	- To track changes to EC DoC - Identify GMDN code per tech file - The list numbers are removed due: - Not a finished device; for further manufacturing - Not a finished device; for further manufacturing - For veterinary/animal health use only - Not a finished device; for further manufacturing - Inactive; no history of sale in EU - Inactive; no history of sale in EU - Inactive; no history of sale in EU - Inactive; no history of sale in EU - Inactive; no history of sale in EU - Inactive; no history of sale in EU - Inactive; no history of sale in EU	2/5/2020
2	- Removed the following from product list: 011-CH-70SL, ChemoClave® Vented Vial Spike, 28mm 011-CL-50, ChemoLock™ Vial Spike 011-CL-74, Locking Universal Vented Vial Spike, ChemoLock™ 011-CL-77, Genie® Closed Vial Spike, ChemoLock™ 011-CL-78, Genie® w/Closed Vial Access Device, 28 mm ChemoLock™ 011-CL-PRIME, ChemoLock™ Priming Device 011-CS-51, Dispensing Pin with 0.2 Micron Vent, CLAVE® 034-CH-77, Punzon para vial 20 mm Genie®, CLAVE® 061-CH-52, Universal Vented Vial Spike, 5 Micron Filter, CLAVE® 061-CH-61, Vial Adapter, 10-50 mL w/.22 Micron Vent, CLAVE® 061-CH-70-S, Universal Vial Access w/Skirt, Large Filter, CLAVE® 061-CH-77, Genie® Closed Vial Access Device, CLAVE® 061-CL-51, Universal Vented Vial Spike, ChemoLock™	- Removal for: - Discontinued; - Agile inactive; for end of life - Addition for: - New LNs - Active LNs issued prior to Agile migration (*) - Incorrectly listed on EC Doc 252.602(**)	4/17/2020

Rev No.	Change Description	Reason for Change	Date of Change
	○ 061-CL-62, 13 mm Closed Vial Spike, ChemoLock™ ○ 061-CL-70, Locking Universal Vented Vial Spike, ChemoLock™ ○ 061-CL-72, 13mm Vented Vial Spike with Tritan, ChemoLock™ ○ 061-CL-77, Genie® Closed Vial Spike, ChemoLock™ ○ 061-CL-78, Genie® w/Closed Vial Access Device; 28mm ChemoLock™ ○ 066-CH-50, SURPLUG® ChemoAccess™ Vial Spike ○ 066-CH-70, SURPLUG® ChemoAccess™ Vented Vial Spike ○ 066-CH-77, SURPLUG® ChemoAccess™ Vial Spike ○ 20132-01, Genie 20mm Closed Vial Spike,CLAVE® ○ CH4077, Genie 20 mm Closed Vial Access Device, CLAVE® (Glow Ring) ○ CH4078, Genie 28 mm Closed Vial Access Device, CLAVE® (Glow Ring) ○ CH-66, 13mm Closed Vial Spike w/0.2 Micron Filter,CLAVE® ○ CH-70T, Locking Universal Vented Vial Spike,CLAVE® ○ CH-70YR, Locking Universal Vented Vial Spike,CLAVE® (Yellow Ring) ○ CH-77, Genie™ Closed Vial Access Device,CLAVE® ○ CH-77-10, Genie™ Closed Vial Access Device,CLAVE®, 10 Units ○ CH-77-5, Genie® Closed Vial Access Device,CLAVE®, 5 Units ○ CH-77YR, Genie® 20mm Closed Vial Spike,CLAVE® (Yellow Ring) ○ CH-78, Genie™ Closed Vial Access Device; 28mmCLAVE® ○ SN1204C-5, Adapter Spike Onko mit Clave • Added the following to product list: ○ 011-CH-70-10, ChemoClave Universal Vented Vial Spike, 10 Units ○ 011-CH-70-15, ChemoClave Universal Vented Vial Spike, 15 Units ○ 011-CH-72-10, ChemoClave™ Vented Vial Spike, 13mm, 10 Units ○ 011-CL-70SXL, ChemoLock™ Vented Vial Spike, ○ 011-CS-51G, Dispensing Pin with 0.2 Micron Vent, Clave™ (Glow Ring)** ○ 011-CS-51RR, Dispensing Pin with 0.2 Micron Vent, Clave™ (Red Ring)** ○ 011-H3703 Locking Universal Vial Spike w/ Clave, 20 Units* ○ 034-CS-51, Dispensing Pin with 0.2 Micron Vent, Clave™ / Clave™ Connector con Mini Perforatore** ○ 034-CS-53 Punzon con conector Clave* ○ CH-80S ChemoClave™ Closed Vial Spike* ○ CH-82 ChemoClave™ 13mm Closed Vial		

Rev No.	Change Description	Reason for Change	Date of Change
	Spike* ○ CS-50 Clave™ Multi-Dose Vial Access Spike* ○ CS-51, Dispensing Pin with 0.2 Micron Vent, Clave™ / Clave™ Connector con Mini Perforatore**		
3	Added: 011-CL-70S-10	• Addition of list number	05/01/2020
4	Removed: AH-72	• Remove list number; for animal health or vet use only	06/11/2020
5	Removed: • 061-CH-62, 13mm Closed Vial Spike, CLAVE® • 061-CH-51, Universal Vented Vial Spike, CLAVE® • 061-CH-63, 20mm Vented Vial Spike w/5 Micron Filter, CLAVE® • 061-CH-70, Locking Universal Vented Vial Spike, CLAVE® • 061-CH-70SL, ChemoClave® Vented Vial Spike, 28mm • 061-CH-72, 13mm Vented Vial Spike with Tritan, CLAVE® • 061-CH-74, Locking Universal Vented Vial Spike, CLAVE® • 061-CH-80, ChemoClave® Closed Vial Spike • 061-CH-80S, ChemoClave® Vial Spike, 20mm • 061-CH-80SL, ChemoClave® Vial Spike, 28mm • 061-CS-40, SINGLE DOSE VIAL ACCESS SPIKE • 061-CS-50, CLAVE Multi-Dose Vial Access Spike • 011-CH3740, Universal Vented Vial Spike, Dry Spike	• Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove LN; discontinued/obsoleted • Remove list number; discontinued	06/11/2020
6	Added: CH-80SL ChemoClave® Vial Spike, 3 Units	• Remove LN; domestic label only	07/10/2020
7	Added: 011-CL-70-10 ChemoLock™ Universal Vented Vial Spike, 10 units	• Addition of new equivalent LN	12/14/2020
8	Removed the following from the product list: • KL-VA001, ChemosafeLock Vial Adapter • KL-VA130, ChemosafeLock Vial Adapter • KL-VA201, ChemosafeLock Vial Adapter • KL-VA202, ChemosafeLock Vial Adapter	• Remove for ○ Private labelled for Terumo only ○ No CE mark on labeling	02/01/2021
9	Updated format to align with new harmonized procedure and L-HSP DoCs; Removed the following sales disabled LNs: 011-C2579; 011-CH3909; 011-CH4070S; 011-CH4070SL; 011-CH-70-C; 011-CH-70S-C; 011-CH-70SL-C; 011-CH-80-C; 011-CH-80S-C; 011-CH-80SL-C; 011-CH-80SXL-C; 011-CL-63; 011-MH-100; 011-MH-55; 011-MH-70; 011-PH-74; 034-CH-70S; 034-CS-51; 034-CS-53; 039-CH-70; 039-CH-80 039-CH-80S; 039-CH-82; 066-CH-51 066-CS-50; 20119-01; 20125-01; 20133-01 420-CS-50; CH3369; CH4070N-AUS; CH-51-5; CH-52; CH-62-5; CH-74-5; CS-60; IB-CH50; IB-CH51; IB-CH62; IB-CH70	Align format with new harmonized procedure and structure to be consistent with L-HSP product DoCs; Remove Agile sales disabled LNs; Add missing Agile sales enabled LNs	16 April 2021

Rev No.	Change Description	Reason for Change	Date of Change
	IB-CH72; IB-CH80; IB-CH80S; IB-CV100 MCH-74 <u>Added:</u> CS-10B; CH-70S-5; CH-10; 011-CL-50		
10	Added: SN1204C; 034-CS-52; 011-H2808	Addition of new equivalent LNs	04 June 2021
11	Added: 011-CL-70S-20; 011-CL-72-10	Addition of new equivalent LNs as replacement for non-011 LNs on this DoC, as follows: CL-70S-20; CL-72-10 The equivalent non-011 LNs will be removed from DoC when the non-011 LNs are confirmed out of stock and no longer in clinical use (e.g. expired inventory).	07-July-2021
12	- Updated format and location of standards table to before the Product List instead of after; and, Removed the GMDN code column from product list and added section into cover page. - Removed CS-10B, Vented Bag Spike with Clave Connector. - Removed 011-H3300, Spiros® Closed Male Luer, Universal Vial Spike w/Clave®, IV Bag Access Device w/Clave®. - Added: 011-CH-51 011-CH-51-10 011-CH-62 011-CH-70-5 011-CH-72 011-CH-74 011-CH-74-10 011-CH-74-15 011-CH-74S 011-CH-74S-10	- Format changes made for alignment with other product DoCs and clarity. - LN CS-10B was incorrectly included in this DoC and is an Admin Set bag spike that should be listed under DoC 252.602 similarly with its equivalent 011-CS-10B LN that is on DoC 252.602 dated 28June2021. - LN 011-H3300 was incorrectly included in this DoC and is an Admin Set with bag spike that is already listed under DoC 252.602 dated 28June2021. - Addition of new 011-CE LNs as replacement for equivalent non-011 LNs on this DoC as follows: CH-51; CH-51-10; CH-62; CH-70-5; 039-CH-72; CH-72; CH-74; CH-74-10; CH-74-15; CH-74S; CH-74S-10. The equivalent non-011 LNs will be removed from DoC when the non-011 LNs are confirmed out of stock and no longer in clinical use (e.g. expired inventory).	22-Oct-2021
13	- Added: 034-CH-70S 034-CS-51 034-CS-53	- Addition for: - Active LNs	06-Jan-2022