

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: Nichelle Cato
Dept: Global Device Regulatory Affairs

Nichelle Cato 17 June 2024
Signature Date

Place of Issue: San Clemente, California	Date of issue: 17 June 2024
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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 ISO 80369-1	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements	2018
EN ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications	2021
EN ISO 8536-4	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed	2020
EN ISO 22413	Transfer sets for pharmaceutical preparations — Requirements and test methods	2021
EN ISO 10993-1	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process	2020
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	2013
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
EN ISO 10993-16	Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables	2017
EN ISO 10993-17	Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009*
EN ISO 11135	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical device	2014+A1:2019
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	2015
EN ISO 11137-2	Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose.	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 ISO 20417	Medical devices — Information to be supplied by the manufacturer	2021
EN 62366	Medical devices - Application of usability engineering to medical devices	2015
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	2018/A1:2021
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	2020

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ASTM F2097	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	2016
ASTM D4332	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	2014
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems	2016
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2016

* As part of re-baselining activities, compliance to the State-of-the Art Standards is in process and will be updated in subsequent revisions

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-53-10	ChemoClave™ Vented Vial Spike, No Skirt, 10 Units
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-70SL	ChemoClave® Vented Vial Spike, 28mm
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

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List Number	Description
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
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

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List Number	Description
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
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

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List Number	Description
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®
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
011-CS-53	Spike with Clave™ Connector
SN1204C	Adapter Spike Onko mit Clave™
OPP3000	5 ml Vial Adapter w/Needlefree Connector

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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
14	- Updated Compliance Standards to align with latest revisions - Format changes made	Compliance to latest version of State of the Art Standards	29-Nov-2022
15	Added: 011-CH-70SL	Reactivation of product for sales in ANZ and addition required to support Manufacturer Evidence in ANZ.	28-March-2023
16	Added: 011-CH-53-10	Addition of 011-CH-53-10 which is a 10-unit equivalent of 011-CH-53. Product is required to support customer demand	18-January-2024

17	Added 011-CS-53	Addition of 011-CS-53 which is the global SKU 011- equivalent of CS-53 that is already in this DoC. Product is required to support customer demand	14 June 2024
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