

DECLARATION OF CONFORMITY

No. 0004 rev.04

Manufacturer	 SOL-MILLENNIUM MEDICAL, INC. 315 Shawnee North Drive, Suite 100 Suwanee, Georgia 30024, USA
Manufacturer's Single Registration Number (SRN)	US-MF-000010890
European Authorized Representative	 Sol-Millennium Europe Sp. z o. o. Twarda 18 00-105 Warsaw Poland
European Authorized Representative's Single Registration Number (SRN)	PL-AR-000010397
Medical Device (Generic device group)	1. Safety Syringe (Manual Retractable) 2. Safety Insulin Syringe (Manual Retractable)
Risk class	see next
Conformity Assessment Procedure	Annex IX, Chapter I and III
We herewith declare that the medical devices listed above meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and the common specifications and harmonized standards listed below. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.	

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Notified Body	Conformity assessment was carried out by the manufacturer with the participation of the Notified Body: BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Identification Number: 2797 The devices have been marked with the CE mark and obtained the MDR Certificate of Conformity No. MDR 766495 R000 valid until 07/11/2027 (dd/mm/yyyy). CE 2797
Validity	This EU Declaration of Conformity has a validity until 07/11/2027 (dd/mm/yyyy), expiration of MDR Certificate.
Place	Suwanee, Georgia 30024, USA
On behalf of the Manufacturer	 4-Jan-23 Manu Kalia Date <i>Director, Quality Assurance</i>
Additional information	Regulatory Affairs Contact Point:  EMEA_QRA@sol-m.com

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LIST OF USED COMMON SPECIFICATIONS AND HARMONIZED STANDARDS		
Standard		Title
EU	Other	
EN ISO 13485:2016	ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
Council Directive 93/42/EEC (MDD)	N/A	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device
(EU) 2017/745 Medical Devices Regulation (MDR)	N/A	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
N/A	21 CFR Part 820	Quality system regulation
N/A	Brazil Collegiate Board Resolution	Brazil Collegiate Board Resolution-RDC No.16 of March 28, 2013
N/A	Australia Therapeutic(Medical Devices) Regulations	Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020
N/A	Canada Medical Devices Regulations	Canada Medical Devices Regulations SOR/98-282
EN ISO7864: 2016	ISO7864: 2016	Sterile hypodermic needles for single use -- Requirements and test methods
EN ISO 7886-1:2018	ISO 7886-1:2017	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
EN ISO 9626:2016	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
EN ISO 8537:2016	ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
EN ISO 80369-7:2017	ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
EN ISO 6009:2016	ISO 6009:2016	Hypodermic needles for single use -- Colour coding for identification
EN ISO 80369-20:2015	ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications -- Part 20: Common test methods
EN ISO 23908:2013	ISO 23908:2011	Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

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Standard		Title
EU	Other	
N/A	21CFR Part 801	TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES PART 801 LABELING
N/A	21CFR Part 830	TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES PART 830 UNIQUE DEVICE IDENTIFICATION
EN ISO 15223-1:2016	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041:2008 +A1:2013	N/A	Information supplied by the manufacturer of medical devices;
N/A	Brazil: RDC ANVISA No.185 2001	ANNEX III. INFORMATION OF LABELS AND INSTRUCTIONS FOR USE OF MEDICAL PRODUCTS
EN 556-1:2001/ /AC:2006	N/A	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
EN ISO 11135:2014/A1:2019	ISO 11135:2014/Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices -- Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/DAmd 1:2018)
EN ISO 11737-1:2018	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	ISO 11737-2:2019	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11138-1:2017	ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2:2017	ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2020	ISO 11607-1:2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	ISO 11607-2:2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

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Standard		Title
EU	Other	
N/A	ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
N/A	ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
N/A	ISTA 3 Series:	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)
EN ISO 780: 2015	ISO 780: 2015	Packaging -- Distribution packaging -- Graphical symbols for handling and storage of packages
EN 868-5: 2018	N/A	Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirement and test methods
N/A	ASTM F1929-2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
N/A	ASTM F88/F88M-15	Standard test method for Seal strength of flexible barrier materials
N/A	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
N/A	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 14971: 2019	ISO 14971: 2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 10993-1:2020	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process
EN ISO 10993-4:2017	ISO 10993-4:2017	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009	ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7 :2008/AC:2009	ISO 10993-7:2008/cor 1 2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
The European Pharmacopoeia (Ph. Eur.)	NA	European Pharmacopoeia (Ph. Eur.) 10th Edition; 2.6.14. Bacterial endotoxins

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Standard		Title
EU	Other	
N/A	USP 43-NF38:2020; <151>	<151> Pyrogen Test (USP Rabbit Test)
N/A	ASTM F756-17	Standard Practice for Assessment of Hemolytic Properties of Materials
N/A	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols



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Generic device group:	Safety Syringe (Manual Retractable)
Device Category CND/ EMDN code	A02010205
GMDN code:	35904
Class	Is+m
Rule	2
Sterility	Sterile
Intended use	The Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

Type/ Models		SOL-CARE Luer Lock Safety Syringe without Needle
Basic UDI-DI code		081006243SSR24K
Reference number	SAP number	Description
120006IM	110101030002	SOL-CARE 3ml Luer Lock Safety Syringe w/o Needle
120007IM	110101030003	SOL-CARE 5ml Luer Lock Safety Syringe w/o Needle
120008IM	110101030004	SOL-CARE 10ml Luer Lock Safety Syringe w/o Needle
120009IM	110101030005	SOL-CARE 20ml Luer Lock Safety Syringe w/o Needle

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Generic device group:	Safety Syringe (Manual Retractable)
Device Category CND/ EMDN code	A02010204
GMDN code:	45042
Class	Ila
Rule	6
Sterility	Sterile
Intended use	The Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

Type/ Models		SOL-CARE Safety Syringe with Fixed Needle
Basic UDI-DI code		081006243SSR64T
Reference number	SAP number	Description
SSR224	SSR224	SOL-CARE 1ml Safety Syringe w/Fixed Needle 23G*1
SSR223	SSR223	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*1 1/2"
100006IMPRO	110101030177	SOL-CARE/PROMAMEC 0.5ml Safety Syringe w/Fixed Needle 23G*1

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Type/ Models		SOL-CARE TB Safety Syringe with Fixed Needle
Basic UDI-DI code		081006243SISR32F
Reference number	SAP number	Description
100006IM	110101030018	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 23G*1
100007IM	110101030019	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 25G*1
100008IM	110101030020	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 26G*1/2
100090IM	110101030021	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 27G*1/2
100009IM	110101030022	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 27G*1
100010IM	110101030023	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 30G*1/2
100023IM	110101030010	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 23G*3/8
100082IM	110101030027	SOL-CARE 1ml Safety Syringe w/Fixed Needle 30G*1/2
100018IM	110101030028	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*5/8
100019IM	110101030030	SOL-CARE 1ml Safety Syringe w/Fixed Needle 27G*1/2
100029IM	110101030031	SOL-CARE 1ml Safety Syringe w/Fixed Needle 29G*1/2
100034IM	110101030032	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*1
100067IM	110101030034	SOL-CARE 1ml Safety Syringe w/Fixed Needle 28G*1/2
100026IM	110101030142	SOL-CARE 1ml Safety Syringe w/Fixed Needle 27G*3/8
100040IM	110401020001	SOL-CARE 1ml Safety Syringe w/Fixed Needle 22G*1 1/2
100025IM	110101030011	SOL-CARE 1ml Safety Syringe w/Fixed Needle 26G*1/2
100011IM	110101030024	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 26G*3/8 IDB
100070IM	110101030035	SOL-CARE 1ml Safety Syringe w/Fixed Needle 26G*3/8 IDB

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Generic device group:	Safety Syringe (Manual Retractable)
Device Category CND/ EMDN code	A02010205
GMDN code:	45042
Class	IIa
Rule	6
Sterility	Sterile
Intended use	The Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

Type/ Models		SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle
Basic UDI-DI code		081006243SSR14H
Reference number	SAP number	Description
100059IM	110101030143	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
100074IM	110101030065	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 20G*1
100075IM	110101030066	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1
100060IM	110101030059	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/4"
100072IM	110101030064	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
100085IM	110101030073	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1
100076IM	110101030067	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
100077IM	110101030068	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1
100086IM	not yet assigned	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 24G*1
100079IM	110101030071	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1
100078IM	110101030070	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*5/8
100099IM	not yet assigned	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1 1/2"
100073IM	110101030062	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/2"
100062IM	110101030060	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4"

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100064IM	110101030061	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4"
100068IM	110101030063	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1 1/4"
140059IM	not yet assigned	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
140072IM	110101030096	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
140076IM	110101030098	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
140086IM	not yet assigned	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 24G*1
140084IM	110101030100	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 20G*1
140075IM	110101030097	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1
140060IM	110101030092	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/4
140085IM	110101030101	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1
140062IM	110101030093	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4
140077IM	110101030099	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1
140065IM	110101030094	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4
SSR231	SSR231	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/2
160072IM	110101030113	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
160059IM	not yet assigned	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
160074IM	110101030122	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 20G*1
160084IM	110101030119	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 20G*1 1/2
160075IM	110101030115	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 21G*1
160062IM	110101030111	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4
160076IM	110101030116	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
160065IM	110101030112	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4
160077IM	110101030118	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 23G*1
160085IM	110101030120	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1
190072IM	110101030129	SOL-CARE 20ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
190059IM	not yet assigned	SOL-CARE 20ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
100072IMPRO	120101030001	SOL-CARE/PROMAMEC 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2

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140072IMPRO	120101030002
160072IMPRO	SSR233
190072IMPRO	SSR234

SOL-CARE/PROMAMEC 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
SOL-CARE/PROMAMEC 10ml Luer Lock Safety Syringe with Exchangeable Needle 21G*1 1/2
SOL-CARE/PROMAMEC 20ml Luer Lock Safety Syringe with Exchangeable Needle 21G*1 1/2



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Generic device group:	Safety Insulin Syringe (Manual Retractable)
Device Category CND/ EMDN code	A02010603 (A02010204)
GMDN code:	34973
Class	Ila
Rule	6
Sterility	Sterile
Intended use	The Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

Type/ Models		SOL-CARE Insulin Safety Syringe with Fixed Needle
Basic UDI-DI code		081006243SIS131
Reference number	SAP number	Description
100001IM	110102020001	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*1/2 (U-100 Insulin Only)
100002IM	110102020002	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 29G*1/2 (U-100 Insulin Only)
100089IM	110102020003	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*8mm (U-100 Insulin Only)
100095IM	110102020038	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*6mm (U-100 Insulin Only)
100017IM	110102020016	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2 (U-100 Insulin Only)
100081IM	110102020019	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*1/2 (U-100 Insulin Only)
100020IM	110102020021	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*8mm (U-100 Insulin Only)
100071IM	110102020022	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 28G*1/2 (U-100 Insulin Only)
100094IM	110102020037	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*6mm (U-100 Insulin Only)
100017IMPRO	110102020034	SOL-CARE/PROMAMEC 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2" (U-100 Insulin Only)

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Type/ Models		SOL-CARE Insulin Safety Syringe with Fixed Needle (U-100 Insulin Only)
Basic UDI-DI code		081006243SIS234
Reference number	SAP number	Description
SIS056	SIS056	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 31G*6mm (U-100 Insulin Only)
SIS055	SIS055	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 31G*6mm (U-100 Insulin Only)

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