



EU DECLARATION OF CONFORMITY
No. 0009 Rev.00

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)	Standard Slip Tip Syringe without Needle Standard Luer Lock Syringe with Blunt Fill Needle Standard Luer Lock Syringe without Needle Insulin Standard Syringe without Needle
Risk class	see next pages
Conformity Assessment Procedure	Annex IX, Chapter I and III
<p>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 harmonized standards listed below.</p> <p>This Declaration of Conformity is issued under the sole responsibility of the manufacturer.</p>	

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<p>Notified Body</p>	<p>Conformity assessment was carried out by the manufacturer with the participation of the Notified Body:</p> <p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Identification Number: 2797</p> <p>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)</p> <p></p>
<p>Validity</p>	<p>This EU Declaration of Conformity has a validity until 07/11/2027 expiration of MDR Certificate. (dd/mm/yyyy)</p>
<p>Place</p>	<p>Suwanee, Georgia 30024, USA</p>
<p>On behalf of the Manufacturer</p>	<p> _____ Manu Kalia <i>Director, Quality Assurance</i></p> <p align="right">09-Nov-2022 _____ Date</p>
<p>Additional information</p>	<p>Regulatory Affairs Contact Point:  EMEA_QRA@sol-m.com</p>

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LIST OF STANDARDS

Standard	Title
EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-7 :2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
EN ISO 8537:2016	Sterile Single use syringes, with or without needle, for insulin
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
EN ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification
EN ISO 23908:2013	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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Generic device group	Standard Slip Tip Syringe without Needle
EMDN code	A020102010202
Class	Im+s
Rule	Rule 2
Sterility	Sterile, Single use
Intended Purpose	The Standard Slip Tip Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.

Reference number	Description
Type/Model: Standard Eccentric Tip Syringe without Needle, Basic UDI-DI: 081006243SR319UU	
180010ET	SOL-M 10ml Eccentric Tip Syringe w/o Needle
P180010ET	SOL-M 10ml Eccentric Tip Syringe w/o Needle
180020ET	SOL-M 20ml Eccentric Tip Syringe w/o Needle
P180020ET	SOL-M 20ml Eccentric Tip Syringe w/o Needle
180050ET	SOL-M 50ml Eccentric Tip Syringe w/o Needle
180060ET	SOL-M 60ml Eccentric Tip Syringe w/o Needle
P180060ET	SOL-M 60ml Eccentric Tip Syringe w/o Needle
180010ETBS	SOL-M 10ml Eccentric Tip Syringe w/o Needle (bulk)
180020ETBS	SOL-M 20ml Eccentric Tip Syringe w/o Needle (bulk)
180050ETBS	SOL-M 50ml Eccentric Tip Syringe w/o Needle (bulk)
P180050ETBS	SOL-M 50ml Eccentric Tip Syringe w/o Needle (bulk)
180060ETBS	SOL-M 60ml Eccentric Tip Syringe w/o Needle (bulk)
Type/Model: Standard Slip Tip Syringe without Needle, Basic UDI-DI: 081006243SR34ZM	
180011	SOL-M 1ml Slip Tip Syringe w/o Needle
P180011	SOL-M 1ml Slip Tip Syringe w/o Needle
180003ST	SOL-M 3ml Slip Tip Syringe w/o Needle

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Reference number	Description
P180003ST	SOL-M 3ml Slip Tip Syringe w/o Needle
180005ST	SOL-M 5ml Slip Tip Syringe w/o Needle
P180005ST	SOL-M 5ml Slip Tip Syringe w/o Needle
180010ST	SOL-M 10ml Slip Tip Syringe w/o Needle
P180010ST	SOL-M 10ml Slip Tip Syringe w/o Needle
180020ST	SOL-M 20ml Slip Tip Syringe w/o Needle
P180020ST	SOL-M 20ml Slip Tip Syringe w/o Needle
180050ST	SOL-M 50ml Slip Tip Syringe w/o Needle
P180050ST	SOL-M 50ml Slip Tip Syringe w/o Needle
P180011BS	SOL-M 1ml Slip Tip Syringe w/o Needle (bulk)
P180003STBS	SOL-M 3ml Slip Tip Syringe w/o Needle (bulk)
P180005STBS	SOL-M 5ml Slip Tip Syringe w/o Needle (bulk)
P180010STBS	SOL-M 10ml Slip Tip Syringe w/o Needle (bulk)
P180020STBS	SOL-M 20ml Slip Tip Syringe w/o Needle (bulk)
P180050STBS	SOL-M 50ml Slip Tip Syringe w/o Needle (bulk)
P180060STBS	SOL-M 60ml Slip Tip Syringe w/o Needle (bulk)
P180011T	SOL-M 1ml Slip Tip Syringe Sterile Convenience Tray
405036	SOL-M/ALK 1ml Luer Slip Allergy Syringe w/o Needle
Type/Model: Standard Slip Tip Syringe without Needle (low dead space / ultra low dead space), Basic UDI-DI: 081006243SR38ZV	
LD180011LDS	SOL-M 1ml Slip Tip Syringe w/o Needle (Ultra low dead space)
180011LDS	SOL-M 1ml Slip Tip Syringe w/o needle (low dead space)
P180011LDSBS	SOL-M 1ml Slip Tip Syringe w/o needle (low dead space, bulk)
P180011LDS	SOL-M 1ml Slip Tip Syringe w/o needle (low dead space)

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Generic device group	Standard Luer Lock Syringe with Blunt Fill Needle
EMDN code	A020102020101
Class	Im+s
Rule	Rule 2
Sterility	Sterile, Single use
Intended Purpose	The Standard Luer Lock Syringe with Blunt Fill Needle is used for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-slit septum covering injection sites.

Reference number	Description
Type/Model: Standard Luer Lock Syringe with Blunt Fill Needle, Basic UDI-DI: 081006243SN318TW	
1831810B	SOL-M 3ml Luer Lock Syringe w/Blunt Fill Needle 18G*1
1831815B	SOL-M 3ml Luer Lock Syringe w/Blunt Fill Needle 18G*1 1/2
1851810B	SOL-M 5ml Luer Lock Syringe w/Blunt Fill Needle 18G*1
1851815B	SOL-M 5ml Luer Lock Syringe w/Blunt Fill Needle 18G*1 1/2
1811810B	SOL-M 10ml Luer Lock Syringe w/Blunt Fill Needle 18G*1
1811815B	SOL-M 10ml Luer Lock Syringe w/Blunt Fill Needle 18G*1 1/2
1821810B	SOL-M 20ml Luer Lock Syringe w/Blunt Fill Needle 18G*1
1821815B	SOL-M 20ml Luer Lock Syringe w/Blunt Fill Needle 18G*1 1/2

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Generic device group	Standard Luer Lock Syringe without Needle
EMDN code	A020102020102
Class	Im+s
Rule	Rule 2
Sterility	Sterile, Single use
Intended Purpose	The Standard Luer Lock Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.

Reference number	Description
Type/Model: Standard Luer Lock Syringe without Needle, Basic UDI-DI: 081006243SR318US	
180001	SOL-M 1ml Luer Lock Syringe w/o Needle (PC)
P180001	SOL-M 1ml Luer Lock Syringe w/o Needle (PP)
180003	SOL-M 3ml Luer Lock Syringe w/o Needle
P180003	SOL-M 3ml Luer Lock Syringe w/o Needle
180005	SOL-M 5ml Luer Lock Syringe w/o Needle
P180005	SOL-M 5ml Luer Lock Syringe w/o Needle
180010	SOL-M 10ml Luer Lock Syringe w/o Needle
P180010	SOL-M 10ml Luer Lock Syringe w/o Needle
180020	SOL-M 20ml Luer Lock Syringe w/o Needle
P180020	SOL-M 20ml Luer Lock Syringe w/o Needle
180030	SOL-M 30ml Luer Lock Syringe w/o Needle
P180030	SOL-M 30ml Luer Lock Syringe w/o Needle
P180050	SOL-M 50ml Luer Lock Syringe w/o Needle
180060	SOL-M 60ml Luer Lock Syringe w/o Needle
P180060	SOL-M 60ml Luer Lock Syringe w/o Needle
P180003BS	SOL-M 3ml Luer Lock Syringe w/o Needle (bulk)
P180005BS	SOL-M 5ml Luer Lock Syringe w/o Needle (bulk)

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Reference number	Description
P180010BS	SOL-M 10ml Luer Lock Syringe w/o Needle (bulk)
P180020BS	SOL-M 20ml Luer Lock Syringe w/o Needle (bulk)
P180030BS	SOL-M 30ml Luer Lock Syringe w/o Needle (bulk)
P180060BS	SOL-M 60ml Luer Lock Syringe w/o Needle (bulk)
C180010BS	SOL-M 10ml Luer Lock Syringe Only (bulk)
180001T	SOL-M 1ml Luer Lock Syringe w/o Needle Tray (PP)
180001TPC	SOL-M 1ml Luer Lock Syringe w/o Needle Tray (PC)
P180003T	SOL-M 3ml Luer Lock Syringe Sterile Convenience Tray
P180005T	SOL-M 5ml Luer Lock Syringe Sterile Convenience Tray
P180010T	SOL-M 10ml Luer Lock Syringe Sterile Convenience Tray
P180020T	SOL-M 20ml Luer Lock Syringe Sterile Convenience Tray
P180030T	SOL-M 30ml Luer Lock Syringe Sterile Convenience Tray
P180060T	SOL-M 60ml Luer Lock Syringe Sterile Convenience Tray
411002	SOL-JECT/ALK 60ml Luer Lock Syringe w/o Needle
Type/Model: Standard Luer Lock Syringe without Needle (low dead space / ultra low dead space), Basic UDI-DI: 081006243SR313UG	
180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP)
P180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) Ultra Low Dead Space
P180001PPBS	SOL-M Luer Lock Syringe without Needle (Bulk, Sterile)

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Generic device group	Insulin Standard Syringe without Needle
EMDN code	A02010602
Class	Im+s
Rule	Rule 2
Sterility	Sterile, Single use
Intended Purpose	The Insulin Standard Syringe without Needle is used to inject insulin into the body with the calibration units of U-100.

Reference number	Description
Type/Model: Insulin Standard Syringe without Needle, Basic UDI-DI: 081006243INS6ZU	
505031	SOL-JECT/ALK 1ml Insulin Syringe w/o Needle
161000	SOL-M 1ml Insulin Syringe Slip Tip w/o Needle

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