

EU DECLARATION OF CONFORMITY
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 Syringe • Standard slip tip syringe with needle (needle aside, exchangeable) • Standard slip tip syringe without needle • Standard luer lock syringe with needle (needle aside, exchangeable) • Standard luer lock syringe with Blunt fill needle • Standard Luer Lock syringe without needle • Standard syringe with fixed needle Insulin Standard Syringe • Insulin standard syringe with fixed needle • Insulin standard syringe without needle • Insulin standard syringe with needle (needle aside, exchangeable)
Risk class	see next pages
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 harmonized standards listed below. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.	

EU DECLARATION OF CONFORMITY
Rev.00

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). 
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 Date Manu Kalia Director, Quality Assurance
Additional information	Regulatory Affairs Contact Point:  EMEA_QRA@sol-m.com

EU DECLARATION OF CONFORMITY

Rev.00

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

EU DECLARATION OF CONFORMITY

Rev.00

Generic device group	Standard Slip Tip Syringe with Needle (needle aside, exchangeable)
EMDN code	A020102010201
Class	IIa
Rule	Rule 6
Sterility	Sterile, Single use
Intended Purpose	The Standard Slip Tip Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.

Reference number	Description
Type/Model: Standard Slip Tip Syringe w/Safety Needle, Basic UDI-DI: 081006243SSC53C	
202215SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
2022125SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
202210SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1
2021125SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
202110SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1
202015SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
2020125SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
202010SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1
1022125SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
1021125SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
1020125SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
102210SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1
52558SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*5/8
52510SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*1
52515SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*1 1/2"
52315SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1 1/2

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
52310SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1
321125SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
320125SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
322125SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
12315SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*1 1/2"
12310SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*1"
12338SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*3/8
12510SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1
12558SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*5/8
125125SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1 1/4
12638SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 26G*3/8
12705SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 27G*1/2
12734SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 27G*3/4
12905SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 29G*1/2
13005SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 30G*1/2
22010SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 20G*1
220125SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
22015SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
22110SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 21G*1
221125SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
22115SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
22210SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 22G*1
222125SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
22215SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
22310SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 23G*1

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
223125SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 23G*11/4
22315SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 23G*1 1/2
22510SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 25G*1
22558SS	SOL-CARE 2ml Slip Tip Syringe w/Safety Needle 25G*5/8
32010SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1
32015SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
32110SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1
32115SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
32210SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1
32215SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
32310SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1
32315SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1 1/2
323125SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1 1/4
32410SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1"
324125SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1 1/4"
32415SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1 1/2"
32515SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*1 1/2"
32510SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*1
32558SS	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*5/8
52010SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 20G*1
52015SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
52110SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 21G*1
52115SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
52210SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 22G*1
52215SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 22G*1 1/2

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
523125SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1 1/4
52410SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1"
524125SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1 1/4"
52415SS	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1 1/2"
101815SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 18G*1 1/2"
102010SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1
102015SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
102110SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1
102115SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
102215SS	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
202115SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
201815SS	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 18G*1 1/2"
SSC299	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*3/8"
SSC301	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*1 1/2"
SSC300	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 23G*1"
SSC303	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*5/8
SSC304	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1 1/4
SSC305	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1 1/2
SSC302	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1
SSC306	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 26G*3/8
SSC308	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 27G*3/4
SSC307	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 27G*1/2
SSC309	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 29G*1/2
SSC310	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 30G*1/2
SSC326	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1 1/4

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
SSC312	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
SSC311	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 20G*1
SSC327	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
SSC314	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
SSC313	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 21G*1
SSC328	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
SSC316	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
SSC315	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 22G*1
SSC317	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1
SSC319	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1 1/4
SSC318	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 23G*1 1/2
SSC320	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1"
SSC321	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1 1/4"
SSC322	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 24G*1 1/2"
SSC325	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*5/8
SSC324	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*1
SSC323	SOL-CARE 3ml Slip Tip Syringe w/Safety Needle 25G*1 1/2"
SSC344	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*5/8
SSC343	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*1
SSC342	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 25G*1 1/2"
SSC341	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1 1/2
SSC340	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1
SSC339	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
SSC338	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1 1/2"
SSC337	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1 1/4"

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
SSC336	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 24G*1"
SSC335	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 23G*1 1/4
SSC334	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
SSC333	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 22G*1
SSC332	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
SSC331	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 21G*1
SSC330	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
SSC329	SOL-CARE 5ml Slip Tip Syringe w/Safety Needle 20G*1
SSC353	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
SSC349	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
SSC348	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 21G*1
SSC354	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
SSC352	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
SSC351	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
SSC350	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 22G*1
SSC347	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
SSC346	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 20G*1
SSC345	SOL-CARE 10ml Slip Tip Syringe w/Safety Needle 18G*1 1/2"
SSC361	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1 1/4
SSC360	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1
SSC355	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 21G*1 1/2
SSC364	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1 1/2
SSC363	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1 1/4
SSC362	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 22G*1
SSC356	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 18G*1 1/2"

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
SSC359	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1 1/2
SSC358	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1 1/4
SSC357	SOL-CARE 20ml Slip Tip Syringe w/Safety Needle 20G*1
Type/Model: Standard Slip Tip Syringe w/Safety Needle (low dead space), Basic UDI-DI: 081006243SSC73G	
12515SS	SOL-CARE 1ml Slip Tip Syringe w/Safety Needle 25G*1 1/2", low dead space
2102790011	FARMATEXA 1ml Slip Tip Syringe w/Safety Needle 27G*1/2 (Double scale, Orange plunger, LDS gasket)
2102790012	FARMATEXA 1ml Slip Tip Syringe w/Safety Needle 25G*5/8(Double scale, Orange plunger, LDS gasket)
Type/Model: Standard Slip Tip Syringe w/Exch needle, Basic UDI-DI: 081006243SN31YT	
181025S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 25G*5/8
182025S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 25G*1"
181026S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 26*1/2"
181027S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 27G*1/2
1810215S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 25G*1 1/2"
1831815ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 18G*1 1/2
1832010ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 20G*1
1832015ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 20G*1 1/2
1832110ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 21G*1
1832115ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 21G*1 1/2
1832210ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 22G*1
1832215ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 22G*1 1/2"
1832310ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 23G *1
1832315ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 23G*1 1/2
18322125ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 22G*1 1/4
18323125ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 23G*1 1/4
1832410ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 24G*1

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
1832510ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 25G*1
18325125ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 25G*1 1/4
1832515ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 25G*1 1/2
1832558ST	SOL-M 3ml Slip Tip Syringe w/Exch Needle 25G*5/8
1851815ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 18G*1 1/2"
1852010ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 20G*1
1852015ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 20G*1 1/2
1852110ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 21G*1
1852115ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 21G *1 1/2
1852210ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 22G*1
18522125ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 22G*1 1/4"
1852215ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 22G*1 1/2
1852310ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 23G*1"
1852315ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 23G*1 1/2"
18523125ST	SOL-M 5ml Slip Tip Syringe w/Exch Needle 23G*1 1/4
1811815ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 18G*1 1/2"
1812010ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 20G*1
1812015ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 20G*1 1/2
1812110ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 21G*1
1812115ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 21G *1 1/2
1812210ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 22G*1
18122125ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 22G*1 1/4
1812215ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 22G*1 1/2
18123125ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 23G*1 1/4"
1812315ST	SOL-M 10ml Slip Tip Syringe w/Exch Needle 23G*1 1/2"

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
18201815ST	SOL-M 20ml Slip Tip Syringe w/Exch Needle 18G*1 1/2"
18202015ST	SOL-M 20ml Slip Tip Syringe w/Exch Needle 20G*1 1/2"
PM_SIR_2.5	Medipresteril 2.5ml Slip Tip Syringe w/Exch Needle 23G*1 1/4"
PM_SIR_5.0	Medipresteril 5ml Slip Tip Syringe w/Exch Needle 23G*1 1/4"
Type/Model: Standard Slip Tip Syringe w/Exch Needle (low dead space), Basic UDI-DI: 081006243SN37Z7	
181023S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 23G*1"
182023S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 23G*1 1/2"
LD182025S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 25G*1
LD181025S	SOL-M 1ml Slip Tip Syringe w/Exch Needle 25G*5/8



EU DECLARATION OF CONFORMITY

Rev.00

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 w/o 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 w/o 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

EU DECLARATION OF CONFORMITY

Rev.00

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 w/o Needle (low dead space), Basic UDI-DI: 081006243SR38ZV	
LD180011LDS	SOL-M 1ml Slip Tip Syringe w/o Needle (low dead space)
180011LDS	SOL-M 1ml Slip Tip Syringe w/o needle (low dead space)
P180011LDBS	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)

EU DECLARATION OF CONFORMITY

Rev.00

Generic device group	Standard Luer Lock Syringe with Needle (needle aside, exchangeable)
EMDN code	A020102020101
Class	IIa
Rule	Rule 6
Sterility	Sterile, Single use
Intended Purpose	The Standard Luer Lock Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.

Reference number	Description
Type/Model: Standard Luer Lock Syringe w/Safety Needle, Basic UDI-DI: 081006243SSC93L	
12338SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 23G*3/8
12310SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 23G*1"
12315SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 23G*1 1/2"
12515SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 25G*1 1/2"
12510SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 25G*1
12558SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 25G*5/8
12638SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 26G*3/8
12705SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 27G*1/2
12734SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 27G*3/4
12905SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 29G*1/2
13005SN	SOL-CARE 1ml Luer Lock Syringe w/Safety Needle 30G*1/2
22010SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 20G*1
220125SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 20G*1 1/4
22015SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 20G*1 1/2
22110SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 21G*1
221125SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 21G*1 1/4
22115SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 22G*1 1/2

Sol-Millennium Medical, Inc.
 315 Shawnee North Drive, Suite 100
 Suwanee, Georgia 30024; USA
 Office 404.973.2200 Fax 770-200-1670
www.sol-m.com

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
22210SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 22G*1
222125SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 22G*1 1/4
22215SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 22G*1 1/2
22310SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 23G*1
223125SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 23G*11/4
22315SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 23G*1 1/2
22510SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 25G*1
22558SN	SOL-CARE 2ml Luer Lock Syringe w/Safety Needle 25G*5/8
32010SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 20G*1
32015SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 20G*1 1/2
32110SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 21G*1
32115SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 21G*1 1/2
32210SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 22G*1
32215SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 22G*1 1/2
32310SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 23G*1
32315SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 23G*1 1/2
323125SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 23G*1 1/4
32410SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 24G*1"
324125SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 24G*1 1/4"
32415SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 24G*1 1/2"
32510SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 25G*1
32558SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 25G*5/8
32515SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 25G*1 1/2"
52010SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 20G*1
52015SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 20G*1 1/2

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
52110SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 21G*1
52115SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 21G*1 1/2
52210SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 22G*1
52215SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 22G*1 1/2
523125SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 23G*1 1/4
52410SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 24G*1"
524125SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 24G*1 1/4"
52415SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 24G*1 1/2"
101815SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 18G*1 1/2"
102010SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 20G*1
102015SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 20G*1 1/2
102110SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 21G*1
102115SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 21G*1 1/2
102210SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 22G*1
102215SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 22G*1 1/2
201815SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 18G*1 1/2"
1020125SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 20G*1 1/4
2020125SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 20G*1 1/4"
202015SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 20G*1 1/2"
202010SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 20G*1"
321125SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 21G*1 1/4"
521125SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 21G*1 1/4
1021125SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 21G*1 1/4
2021125SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 21G*1 1/4"
202115SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 21G*1 1/2"

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
202110SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 21G*1"
322125SN	SOL-CARE 3ml Luer Lock Syringe w/Safety Needle 22G*1 1/4"
522125SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 22G*1 1/4"
1022125SN	SOL-CARE 10ml Luer Lock Syringe w/Safety Needle 22G*1 1/4"
2022125SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 22G*1 1/4"
202215SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 22G*1 1/2"
202210SN	SOL-CARE 20ml Luer Lock Syringe w/Safety Needle 22G*1"
52315SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 23G*1 1/2"
52310SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 23G*1"
52558SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 25G*5/8"
52515SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 25G*1 1/2"
52510SN	SOL-CARE 5ml Luer Lock Syringe w/Safety Needle 25G*1"
Type/Model: Standard Luer Lock Syringe w/Exch Needle, Basic UDI-DI: 081006243SN32YV	
18323125	SOL-M 3ml Luer Lock Syringe w/Exch Needle 23G*1 1/4"
18523125	SOL-M 5ml Luer Lock Syringe w/Exch Needle 23G*1 1/4"
1812010	SOL-M 10ml Luer Lock Syringe w/Exch Needle 20G*1"
1812015	SOL-M 10ml Luer Lock Syringe w/Exch Needle 20G*1 1/2"
1812110	SOL-M 10ml Luer Lock Syringe w/Exch Needle 21G*1"
1812115	SOL-M 10ml Luer Lock Syringe w/Exch Needle 21G*1 1/2"
1812210	SOL-M 10ml Luer Lock Syringe w/Exch Needle 22G*1"
1831815	SOL-M 3ml Luer Lock Syringe w/Exch Needle 18G*1 1/2"
1832010	SOL-M 3ml Luer Lock Syringe w/Exch Needle 20G*1"
1832015	SOL-M 3ml Luer Lock Syringe w/Exch Needle 20G*1 1/2"
1832110	SOL-M 3ml Luer Lock Syringe w/Exch Needle 21G*1"
1832115	SOL-M 3ml Luer Lock Syringe w/Exch Needle 21G*1 1/2"

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
1832210	SOL-M 3ml Luer Lock Syringe w/Exch Needle 22G*1
18322125	SOL-M 3ml Luer Lock Syringe w/Exch Needle 22G*1 1/4
1832215	SOL-M 3ml Luer Lock Syringe w/Exch Needle 22G*1 1/2
1832310	SOL-M 3ml Luer Lock Syringe w/Exch Needle 23G*1
1832510	SOL-M 3ml Luer Lock Syringe w/Exch Needle 25G*1
1832515	SOL-M 3ml Luer Lock Syringe w/Exch Needle 25G*1 1/2
1832558	SOL-M 3ml Luer Lock Syringe w/Exch Needle 25G*5/8
1852010	SOL-M 5ml Luer Lock Syringe w/Exch Needle 20G*1
1852015	SOL-M 5ml Luer Lock Syringe w/Exch Needle 20G*1 1/2
1852110	SOL-M 5ml Luer Lock Syringe w/Exch Needle 21G*1
1852115	SOL-M 5ml Luer Lock Syringe w/Exch Needle 21G*1 1/2
1852210	SOL-M 5ml Luer Lock Syringe w/Exch Needle 22G*1
1852215	SOL-M 5ml Luer Lock Syringe w/Exch Needle 22G*1 1/2
1832315	SOL-M 3ml Luer Lock Syringe w/Exch Needle 23G*1 1/2
1832410	SOL-M 3ml Luer Lock Syringe w/Exch Needle 24G*1
18325125	SOL-M 3ml Luer Lock Syringe w/Exch Needle 25G*1 1/4
1851815	SOL-M 5ml Luer Lock Syringe w/Exch Needle 18G*1 1/2"
18522125	SOL-M 5ml Luer Lock Syringe w/Exch Needle 22G*1 1/4"
1852315	SOL-M 5ml Luer Lock Syringe w/Exch Needle 23G*1 1/2"
1852310	SOL-M 5ml Luer Lock Syringe w/Exch Needle 23G*1"
1811815	SOL-M 10ml Luer Lock Syringe w/Exch Needle 18G*1 1/2"
1812215	SOL-M 10ml Luer Lock Syringe w/Exch Needle 22G*1 1/2
18122125	SOL-M 10ml Luer Lock Syringe w/Exch Needle 22G*1 1/4
1812315	SOL-M 10ml Luer Lock Syringe w/Exch Needle 23G*1 1/2"
18123125	SOL-M 10ml Luer Lock Syringe w/Exch Needle 23G*1 1/4"

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
18202015	SOL-M 20ml Luer Lock Syringe w/Exch Needle 20G*1 1/2"
18201815	SOL-M 20ml Luer Lock Syringe w/Exch Needle 18G*1 1/2"
1852110T	SOL-M 5ml Luer Lock Syringe w/Exch Needle Tray 21G*1
1832110T	SOL-M 3ml Luer Lock Syringe w/Exch Needle Tray 21G*1
1852010T	SOL-M 5ml Luer Lock Syringe w/Exch Needle Tray 20G*1
1832210T	SOL-M 3ml Luer Lock Syringe w/Exch Needle Tray 22G*1
1832310T	SOL-M 3ml Luer Lock Syringe w/Exch Needle Tray 23G*1
1832510T	SOL-M 3ml Luer Lock Syringe w/Exch Needle Tray 25G*1"
110101120011	SOL-M 10ml Luer Lock Syringe w/Exch Needle Tray 20G*1
110101120012	SOL-M 10ml Luer Lock Syringe w/Exch Needle Tray 21G*1
Type/Model: Standard Luer Lock Syringe w/Exch Needle (low dead space), Basic UDI-DI: 081006243SN38Z9	
181023L	SOL-M 1ml Luer Lock Syringe w/Exch Needle 23G*1" (low dead space)
182023L	SOL-M 1ml Luer Lock Syringe w/Exch Needle 23G*1 1/2" (low dead space)
182025L	SOL-M 1ml Luer Lock Syringe w/Exch Needle 25G*1" (low dead space)
1810258L	SOL-M 1ml Luer Lock Syringe w/Exch Needle 25G*5/8" (low dead space)
1810215L	SOL-M 1ml Luer Lock Syringe w/Exch Needle 25G*1 1/2" (low dead space)

EU DECLARATION OF CONFORMITY
Rev.00

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 w/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

EU DECLARATION OF CONFORMITY

Rev.00

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 w/o 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
P180001PPBS	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) (bulk)
P180003BS	SOL-M 3ml Luer Lock Syringe w/o Needle (bulk)

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
P180005BS	SOL-M 5ml Luer Lock Syringe w/o Needle (bulk)
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 w/o Needle (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)

EU DECLARATION OF CONFORMITY

Rev.00

Generic device group	Standard Syringe with Fixed Needle
EMDN code	A02010204
Class	Ila
Rule	Rule 6
Sterility	Sterile, Single use
Intended Purpose	The Standard Syringe with Fixed Needle is used to inject fluids into, or withdraw fluids from, the body.

Reference number	Description
Type/Model: Standard Syringe with Fixed Needle, Basic UDI-DI: 081006243SN33YX	
405038	SOL-M/ALK 1ml Allergy Syringe w/Fixed Needle 27G*1/2" (PE Bag)
405043	SOL-M/ALK 1ml Allergy Syringe w/Fixed Needle 27G*1/2" (multi-packs)
181025T	SOL-M 1ml Syringe Tray 25G*5/8"
182025T	SOL-M 1ml Syringe Tray 25G*1"
181023T	SOL-M 1ml Mixing Syringe Tray 23G*1/2
181527T	SOL-M 0.5ml Allergy Syringe Tray 27G*3/8
180527T	SOL-M 0.5ml Allergy Syringe Tray 27G*1/2
181026T	SOL-M 1ml Allergy Syringe Tray 26G*1/2
181027T	SOL-M 1ml Allergy Syringe Tray 27G*1/2
181527IDBT	SOL-M 0.5ml Allergy Syringe Tray 27G*3/8 IDB
181026IDBT	SOL-M 1ml Allergy Syringe Tray 26G*3/8 IDB
181126IDBT	SOL-M 1ml Allergy Syringe Tray 26G*1/2 IDB
181027IDBT	SOL-M 1ml Allergy Syringe Tray 27G*3/8 IDB
405010	SOL-JECT/ALK 1ml Safety Syringe Allergy Tray 27G*1/2"
SFN001	SOL-M 0.3ml Syringe w/Fixed Needle 31G*6mm
180523	SOL-M 0.5ml Syringe with Fixed Needle 23G*1"

Sol-Millennium Medical, Inc.
315 Shawnee North Drive, Suite 100
Suwanee, Georgia 30024; USA
Office 404.973.2200 Fax 770-200-1670
www.sol-m.com

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
181525	SOL-M 0.5ml Syringe with Fixed Needle 25G 5/8"
180525	SOL-M 0.5ml Syringe with Fixed needle 25G 1"
181023	SOL-M 1ml Syringe with Fixed Needle 23G 1"
182025	SOL-M 1ml Syringe w/Fixed Needle 25G*1
180527	SOL-M 0.5ml Syringe w/Fixed Needle 27G*1/2
181025	SOL-M 1ml Syringe w/Fixed Needle 25G*5/8
181026	SOL-M 1ml Syringe w/Fixed Needle 26G*1/2
181027	SOL-M 1ml Syringe w/Fixed Needle 27G*1/2
181026IDB	SOL-M 1ml Syringe w/Fixed Needle 26G*3/8 IDB
181026B	SOL-M 1ml Syringe w/Fixed Needle 26G*1/2" (PE bag)
181027B	SOL-M 1ml Syringe w/Fixed Needle 27G*1/2" (PE bag)
181025B	SOL-M 1ml Syringe w/Fixed Needle 25G*5/8" (PE bag)
181023B	SOL-M 1ml Syringe w/Fixed Needle 23G*1/2" (PE bag)

EU DECLARATION OF CONFORMITY

Rev.00

Generic device group	Insulin Standard Syringe with Fixed Needle
EMDN code	A02010601
Class	Ila
Rule	Rule 6
Sterility	Sterile, Single use
Intended Purpose	The Insulin Standard Syringe with Fixed Needle is used to inject insulin into the body with the calibration units of U-100.

Reference number	Description
Type/Model: Insulin Standard Syringe w/Fixed Needle, Basic UDI-DI: 081006243INS1ZJ	
1632912B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 29G*1/2 (PE Bag)
1633012B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 30G*1/2 (PE Bag)
1633051B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 30G*8mm (PE Bag)
1633151B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 31G*8mm (PE Bag)
1652912B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 29G*1/2 (PE Bag)
1653012B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 30G*1/2 (PE Bag)
1653051	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 30G*8mm
1653051B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 30G*8mm (PE Bag)
1653151B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 31G*8mm (PE Bag)
1612912B	SOL-M 1ml Insulin Syringe w/Fixed Needle 29G*1/2 (PE Bag)
1613012B	SOL-M 1ml Insulin Syringe w/Fixed Needle 30G*1/2 (PE Bag)
1613051B	SOL-M 1ml Insulin Syringe w/Fixed Needle 30G*8mm (PE Bag)
1613151B	SOL-M 1ml Insulin Syringe w/Fixed Needle 31G*8mm (PE Bag)
1613051	SOL-M 1ml Insulin Syringe w/Fixed Needle 30G*8mm
1653151	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 31G*8mm (1/2 unit marking)

Sol-Millennium Medical, Inc.
315 Shawnee North Drive, Suite 100
Suwanee, Georgia 30024; USA
Office 404.973.2200 Fax 770-200-1670
www.sol-m.com

EU DECLARATION OF CONFORMITY

Rev.00

Reference number	Description
1613151	SOL-M 1ml Insulin Syringe w/Fixed Needle 31G*8mm
1613012	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 31G*6mm
1612512	SOL-M 1ml Insulin Syringe w/Fixed Needle 31G*6mm
165311564	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 31G*6mm
161311564	SOL-M 1ml Insulin Syringe w/Fixed Needle 31G*6mm
1612812B	SOL-M 1ml Insulin Syringe w/Fixed Needle 28G*1/2 (PE Bag)
1612712B	SOL-M 1ml Insulin Syringe w/Fixed Needle 27G*1/2 (PE Bag)
1612758B	SOL-M 1ml Insulin Syringe w/Fixed Needle 27G*5/8 (PE Bag)
1652812B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 28G*1/2 (PE Bag)
1652712B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 27G*1/2 (PE Bag)
161311564B	SOL-M 1ml Insulin Syringe w/Fixed Needle 31G*6mm (PE Bag)
163311564B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 31Gx6mm (PE Bag) (1/2 unit marking)
165311564B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 31Gx6mm (PE Bag) (1/2 unit marking)
6001	HTL/droplet 0.3ml Insulin Syringe 31G * 6mm (PE Bag, 100pcs/box)
6020	HTL/droplet 0.3ml Insulin Syringe 31G * 6mm (PE Bag, 90pcs/box)
6012	HTL/droplet 0.3ml Insulin Syringe 30G * 8mm (PE Bag, 100pcs/box)
6006	HTL/droplet 0.3ml Insulin Syringe 31G * 8mm (PE Bag, 100pcs/box)
6025	HTL/droplet 0.3ml Insulin Syringe 31G * 8mm (PE Bag, 90pcs/box)
6052	HTL/droplet 0.3ml Insulin Syringe 29G * 12.5mm (PE Bag, 100pcs/box)
6009	HTL/droplet 0.3ml Insulin Syringe 30G * 12.5mm (PE Bag, 100pcs/box)
6028	HTL/droplet 0.3ml Insulin Syringe 30G * 12.5mm (PE Bag, 90pcs/box)
6002	HTL/droplet 0.5ml Insulin Syringe 31G * 6mm (PE Bag, 100pcs/box)
6021	HTL/droplet 0.5ml Insulin Syringe 31G * 6mm (PE Bag, 90pcs/box)
s6013	HTL/droplet 0.5ml Insulin Syringe 30G * 8mm (PE Bag, 100pcs/box)
6005	HTL/droplet 0.5ml Insulin Syringe 31G * 8mm (PE Bag, 100pcs/box)

EU DECLARATION OF CONFORMITY
Rev.00

Reference number	Description
6024	HTL/droplet 0.5ml Insulin Syringe 31G * 8mm (PE Bag, 90pcs/box)
6051	HTL/droplet 0.5ml Insulin Syringe 29G * 12.5mm (PE Bag, 100pcs/box)
6008	HTL/droplet 0.5ml Insulin Syringe 30G * 12.5mm (PE Bag, 100pcs/box)
6027	HTL/droplet 0.5ml Insulin Syringe 30G * 12.5mm (PE Bag, 90pcs/box)
6003	HTL/droplet 1ml Insulin Syringe 31G * 6mm (PE Bag, 100pcs/box)
6011	HTL/droplet 1ml Insulin Syringe 30G * 8mm (PE Bag, 100pcs/box)
6004	HTL/droplet 1ml Insulin Syringe 31G * 8mm (PE Bag, 100pcs/box)
6050	HTL/droplet 1ml Insulin Syringe 29G * 12.5mm (PE Bag, 100pcs/box)
6007	HTL/droplet 1ml Insulin Syringe 30G * 12.5mm (PE Bag, 100pcs/box)
6022	HTL/droplet 1ml Insulin Syringe 31G * 6mm (PE Bag, 90pcs/box)
6026	HTL/droplet 1ml Insulin Syringe 30G * 12.5mm (PE Bag, 90pcs/box)
6023	HTL/droplet 1ml Insulin Syringe 31G * 8mm (PE Bag, 90pcs/box)

EU DECLARATION OF CONFORMITY
Rev.00

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 w/o 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

EU DECLARATION OF CONFORMITY

Rev.00

Generic device group	Insulin Standard Syringe with Needle (needle aside, exchangeable)
EMDN code	A02010699
Class	IIa
Rule	Rule 6
Sterility	Sterile, Single use
Intended Purpose	The Insulin Standard Syringe with Needle is used to inject insulin into the body with the calibration units of U-100.

Reference number	Description
Type/Model: Insulin Standard Syringe Slip Tip w/Exch needle, Basic UDI-DI: 081006243INS3ZN	
110102010037	SOL-M 1ml Insulin Syringe Slip Tip w/Exch Needle 25G*1/2
505040	SOL-M/ALK 1ml Insulin Syringe Slip Tip w/Exch Needle 30G*8mm
505039	SOL-M/ALK 1ml Insulin Syringe Slip Tip w/Exch Needle 30G*1/2
505038	SOL-M/ALK 1ml Insulin Syringe Slip Tip w/Exch Needle 29G*1/2
505037	SOL-M/ALK 1ml Insulin Syringe Slip Tip w/Exch Needle 25G*1
Type/Model: Insulin Standard Syringe Slip Tip w/Exch Needle (low dead space), Basic UDI-DI: 081006243INS5ZS	
012558S	SOL-M 1ml Insulin Syringe Slip Tip w/Exch Needle 25G*5/8 (low dead space tip, orange plunger)
Type/Model: Insulin Standard Syringe Luer Lock w/Safety Needle, Basic UDI-DI: 081006243INS823	
12905SNI	SOL-CARE 1ml Luer Lock Insulin Syringe w/Safety Needle 29G*1/2
13005SNI	SOL-CARE 1ml Luer Lock Insulin Syringe w/Safety Needle 30G*1/2

-END of DOCUMENT-