

**EU Declaration of Conformity  
TF-05 rev.10**

**Annex IV of Regulation (EU) 2017/745**

<b>Manufacturer:</b>	SOL-Millennium Medical, Inc. 311 S Wacker Drive, Suite 4100 Chicago, Illinois, 60606, UNITED STATES
<b>Manufacturer's Single Registration Number (SRN):</b>	US-MF-000010890
<b>European Authorized Representative:</b>	Sol-Millennium Europe Sp. z o. o. Twarda 18, 00-105 Warsaw, Poland
<b>European Authorized Representative's Single Registration Number (SRN):</b>	PL-AR-000010397
<b>Technical File reference:</b>	TF-05
<b>Basic UDI-DI:</b>	See Attachment 1
<b>Device Identification:</b>	See Attachment 1
<b>Risk Class and Rule(s):</b>	See Attachment 1
<b>Notified Body:</b>	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP, Amsterdam Netherlands Certificate number MDR 766495 R000
<b>Notified Body Number:</b>	2797

**Declaration Statement:**

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.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

### Medical Device (Generic device group)

- Standard Syringe
  - Standard Slip Tip syringe with safety needle (needle aside, exchangeable)
  - Standard Slip Tip Syringe w/Safety Needle (low dead space)
  - Standard Slip Tip Syringe w/Exch Needle
  - Standard Slip Tip Syringe w/Exch Needle (low dead space)
- Standard Slip Tip Syringe without Needle
  - Standard Eccentric Tip Syringe w/o Needle
  - Standard Slip Tip Syringe w/o Needle
  - Standard Slip Tip Syringe w/o Needle (low dead space)
- Standard Luer Lock Syringe with Needle (needle aside, exchangeable)
  - Standard Luer Lock Syringe w/Safety Needle
  - Standard Luer Lock Syringe w/Exch Needle
  - Standard Luer Lock Syringe w/Exch Needle (low dead space)
- Standard Luer Lock Syringe with Blunt Fill Needle
- Standard Luer Lock Syringe without Needle
  - Standard Luer Lock Syringe w/o Needle
  - Standard Luer Lock Syringe w/o Needle (low dead space)
- Standard Luer Lock Syringe without Needle (suitable for use with power-driven syringe pumps)
- Standard Syringe with Fixed Needle
- Insulin Standard Syringe with fixed needle
- Insulin Standard syringe without needle
- Insulin Standard syringe with needle (needle aside, exchangeable)
  - Insulin Standard Syringe Slip Tip w/Exch Needle (low dead space)
  - Insulin Standard Syringe Slip Tip w/Exch Needle (low dead space)
  - Insulin Standard Syringe Luer Lock w/Safety Needle
- Syringe Tip Cap

#### GLOBAL CORPORATE HEADQUARTERS

#### Sol-Millennium Medical Inc.

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

## EU Declaration of Conformity TF-05 rev.10

**Conformity Assessment Procedure**

Annex IX, Chapter I and III

**Additional information**

Regulatory Affairs Contact Point:



[EMEA\\_QRA@sol-m.com](mailto:EMEA_QRA@sol-m.com)

Chicago, Illinois, 60606, UNITED STATES

Signed by:

*Edward Roles*



Signer Name: Edward Roles

Signing Reason: I approve this document

Signing Time: 1/12/2026 | 7:13:33 AM PST

~~Edward Roles~~

Director of RA, PRRC

Edward Roles 53B949F396BDA3C873ABC8A9

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

+1-833-637-0857

[info@solm.com](mailto:info@solm.com)

[www.solm.com](http://www.solm.com)

Page 3 of 24

**EU Declaration of Conformity  
TF-05 rev.10**

**Attachment 1**

<b>Generic device group</b>	Standard Syringe
<b>EMDN code</b>	A020102010201
<b>Class</b>	IIa
<b>Rule</b>	Rule 6
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	The Standard Syringe with Needle is used to inject fluids into, or withdraw fluids from, the body.

<b>Type/Model: Standard Slip Tip Syringe with safety needle (needle aside, exchangeable) Basic UDI-DI: 081006243SSC53C</b>	
<b>REF number</b>	<b>Product name and Description</b>
202215SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1 1/2
2022125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1 1/4
202210SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1
2021125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1 1/4
202110SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1
202015SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1 1/2
2020125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1 1/4
202010SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1
1022125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1 1/4
1021125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1 1/4
1020125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1 1/4
102210SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1
52558SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*5/8
52510SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*1
52515SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*1 1/2"
52315SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1 1/2
52310SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1
321125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1 1/4
320125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1 1/4
322125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1 1/4
12315SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*1 1/2"
12310SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*1"
12338SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*3/8
12510SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1
12558SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*5/8
125125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1 1/4
12638SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 26G*3/8

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

12705SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 27G*1/2
12734SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 27G*3/4
12905SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 29G*1/2
13005SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 30G*1/2
22010SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 20G*1
220125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 20G*1 1/4
22015SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 20G*1 1/2
22110SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 21G*1
221125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 21G*1 1/4
22115SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 21G*1 1/2
22210SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 22G*1
222125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 22G*1 1/4
22215SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 22G*1 1/2
22310SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 23G*1
223125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 23G*11/4
22315SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 23G*1 1/2
22510SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 25G*1
22558SS	SOL-CARE Slip Tip Syringe with Safety Needle, 2ml, 25G*5/8
32010SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1
32015SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1 1/2
32110SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1
32115SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1 1/2
32210SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1
32215SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1 1/2
32310SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1
32315SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1 1/2
323125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1 1/4
32410SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1"
324125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1 1/4"
32415SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1 1/2"
32515SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*1 1/2"
32510SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*1
32558SS	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*5/8
52010SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 20G*1
52015SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 20G*1 1/2
52110SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 21G*1
52115SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 21G*1 1/2
52210SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 22G*1

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

52215SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 22G*1 1/2
523125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1 1/4
52410SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1"
524125SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1 1/4"
52415SS	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1 1/2"
101815SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 18G*1 1/2"
102010SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1
102015SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1 1/2
102110SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1
102115SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1 1/2
102215SS	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1 1/2
202115SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1 1/2
201815SS	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 18G*1 1/2"
SSC299	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*3/8"
SSC301	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*1 1/2"
SSC300	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 23G*1"
SSC303	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*5/8
SSC304	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1 1/4
SSC305	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1 1/2
SSC302	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1
SSC306	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 26G*3/8
SSC308	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 27G*3/4
SSC307	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 27G*1/2
SSC309	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 29G*1/2
SSC310	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 30G*1/2
SSC326	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1 1/4
SSC312	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1 1/2
SSC311	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 20G*1
SSC327	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1 1/4
SSC314	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1 1/2
SSC313	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 21G*1
SSC328	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1 1/4
SSC316	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1 1/2
SSC315	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 22G*1
SSC317	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1
SSC319	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1 1/4
SSC318	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 23G*1 1/2
SSC320	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1"

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

SSC321	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1 1/4"
SSC322	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 24G*1 1/2"
SSC325	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*5/8
SSC324	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*1
SSC323	SOL-CARE Slip Tip Syringe with Safety Needle, 3ml, 25G*1 1/2"
SSC344	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*5/8
SSC343	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*1
SSC342	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 25G*1 1/2"
SSC341	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1 1/2
SSC340	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1
SSC339	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 22G*1 1/4
SSC338	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1 1/2"
SSC337	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1 1/4"
SSC336	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 24G*1"
SSC335	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 23G*1 1/4
SSC334	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 22G*1 1/2
SSC333	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 22G*1
SSC332	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 21G*1 1/2
SSC331	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 21G*1
SSC330	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 20G*1 1/2
SSC329	SOL-CARE Slip Tip Syringe with Safety Needle, 5ml, 20G*1
SSC353	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1 1/4
SSC349	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1 1/2
SSC348	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 21G*1
SSC354	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1 1/4
SSC352	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1 1/4
SSC351	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1 1/2
SSC350	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 22G*1
SSC347	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1 1/2
SSC346	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 20G*1
SSC345	SOL-CARE Slip Tip Syringe with Safety Needle, 10ml, 18G*1 1/2"
SSC361	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1 1/4
SSC360	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1
SSC355	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 21G*1 1/2
SSC364	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1 1/2
SSC363	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1 1/4
SSC362	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 22G*1
SSC356	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 18G*1 1/2"

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

SSC359	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1 1/2
SSC358	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1 1/4
SSC357	SOL-CARE Slip Tip Syringe with Safety Needle, 20ml, 20G*1

<b>Type/Model: Standard Slip Tip Syringe with Safety Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243SSC73G</b>	
REF number	Product name and Description
12515SS	SOL-CARE Slip Tip Syringe with Safety Needle, 1ml, 25G*1 1/2", low dead space

<b>Type/Model: Standard Slip Tip Syringe with Exchangeable needle</b>	
<b>Basic UDI-DI: 081006243SN31YT</b>	
REF number	Product name and Description
181025S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 25G*5/8
182025S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 25G*1"
181026S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 26*1/2"
181027S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 27G*1/2
1810215S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 25G*1 1/2''
1831815ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 18G*1 1/2
1832010ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 20G*1
1832015ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 20G*1 1/2
1832110ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 21G*1
1832115ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 21G*1 1/2
1832210ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 22G*1
1832215ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 22G*1 1/2"
1832310ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 23G *1
1832315ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 23G*1 1/2
18322125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 22G*1 1/4
18323125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 23G*1 1/4
1832410ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 24G*1
1832510ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 25G*1
18325125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 25G*1 1/4
1832515ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 25G*1 1/2
1832558ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 3ml, 25G*5/8
1851815ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 18G*1 1/2"
1852010ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 20G*1
1852015ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 20G*1 1/2
1852110ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 21G*1
1852115ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 21G *1 1/2

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

1852210ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 22G*1
18522125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 22G*1 1/4"
1852215ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 22G*1 1/2"
1852310ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 23G*1"
1852315ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 23G*1 1/2"
18523125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 5ml, 23G*1 1/4"
1811815ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 18G*1 1/2"
1812010ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 20G*1
1812015ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 20G*1 1/2"
1812110ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 21G*1
1812115ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 21G *1 1/2"
1812210ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 22G*1
18122125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 22G*1 1/4"
1812215ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 22G*1 1/2"
18123125ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 23G*1 1/4"
1812315ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 10ml, 23G*1 1/2"
18201815ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 20ml, 18G*1 1/2"
18202015ST	SOL-M Slip Tip Syringe with Exchangeable Needle, 20ml, 20G*1 1/2"

<b>Type/Model: Standard Slip Tip Syringe with Exchangeable Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243SN37Z7</b>	
<b>REF number</b>	<b>Product name and Description</b>
181023S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 23G*1"
182023S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 23G*1 1/2''
LD182025S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 25G*1
LD181025S	SOL-M Slip Tip Syringe with Exchangeable Needle, 1ml, 25G*5/8

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

<b>Generic device group</b>	Standard Slip Tip Syringe without Needle
<b>EMDN code</b>	A020102010202
<b>Class</b>	Im+s
<b>Rule</b>	Rule 2
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	The Standard Slip Tip Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.

<b>Type/Model: Standard Eccentric Tip Syringe without Needle</b>	
<b>Basic UDI-DI: 081006243SR319UU</b>	
REF number	Product name and Description
180010ET	SOL-M Eccentric Tip Syringe without Needle, 10ml
P180010ET	SOL-M Eccentric Tip Syringe without Needle, 10ml
180020ET	SOL-M Eccentric Tip Syringe without Needle, 20ml
P180020ET	SOL-M Eccentric Tip Syringe without Needle, 20ml
180050ET	SOL-M Eccentric Tip Syringe without Needle, 50ml
180060ET	SOL-M Eccentric Tip Syringe without Needle, 60ml
P180060ET	SOL-M Eccentric Tip Syringe without Needle, 60ml
180010ETBS	SOL-M Eccentric Tip Syringe without Needle, 10ml (bulk)
180020ETBS	SOL-M Eccentric Tip Syringe without Needle, 20ml (bulk)
180050ETBS	SOL-M Eccentric Tip Syringe without Needle, 50ml (bulk)
P180050ETBS	SOL-M Eccentric Tip Syringe without Needle, 50ml (bulk)
180060ETBS	SOL-M Eccentric Tip Syringe without Needle, 60ml (bulk)

<b>Type/Model: Standard Slip Tip Syringe without Needle</b>	
<b>Basic UDI-DI: 081006243SR34ZM</b>	
REF number	Product name and Description
180011	SOL-M Slip Tip Syringe without Needle, 1ml
P180011	SOL-M Slip Tip Syringe without Needle, 1ml
180003ST	SOL-M Slip Tip Syringe without Needle, 3ml
P180003ST	SOL-M Slip Tip Syringe without Needle, 3ml
180005ST	SOL-M Slip Tip Syringe without Needle, 5ml
P180005ST	SOL-M Slip Tip Syringe without Needle, 5ml
180010ST	SOL-M Slip Tip Syringe without Needle, 10ml
P180010ST	SOL-M Slip Tip Syringe without Needle, 10ml
180020ST	SOL-M Slip Tip Syringe without Needle, 20ml
P180020ST	SOL-M Slip Tip Syringe without Needle, 20ml
180050ST	SOL-M Slip Tip Syringe without Needle, 50ml
P180050ST	SOL-M Slip Tip Syringe without Needle, 50ml
P180011BS	SOL-M Slip Tip Syringe without Needle, 1ml (bulk)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

P180003STBS	SOL-M Slip Tip Syringe without Needle, 3ml (bulk)
P180005STBS	SOL-M Slip Tip Syringe without Needle, 5ml (bulk)
P180010STBS	SOL-M Slip Tip Syringe without Needle, 10ml (bulk)
P180020STBS	SOL-M Slip Tip Syringe without Needle, 20ml (bulk)
P180050STBS	SOL-M Slip Tip Syringe without Needle, 50ml (bulk)
P180060STBS	SOL-M Slip Tip Syringe without Needle, 60ml (bulk)
P180011T	SOL-M Slip Tip Syringe Sterile Convenience Tray, 1ml
405036	SOL-M Allergy Syringe, 1ml (ALK)
P180030ST	SOL-M Slip Tip Syringe without Needle, 30ml
P180060ST	SOL-M Slip Tip Syringe without Needle, 60ml

<b>Type/Model: Standard Slip Tip Syringe without Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243SR38ZV</b>	
<b>REF number</b>	<b>Product name and Description</b>
LD180011LDS	SOL-M Slip Tip Syringe without Needle, 1ml (low dead space)
180011LDS	SOL-M Slip Tip Syringe without Needle, 1ml (low dead space)
P180011LDSBS	SOL-M Slip Tip Syringe without Needle, 1ml (low dead space, bulk)
P180011LDS	SOL-M Slip Tip Syringe without Needle, 1ml (low dead space)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

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

<b>Type/Model: Standard Luer Lock Syringe with Safety Needle Basic UDI-DI: 081006243SSC93L</b>	
<b>REF number</b>	<b>Product name and Description</b>
12338SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 23G*3/8
12310SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 23G*1"
12315SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 23G*1 1/2"
12515SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 25G*1 1/2"
12510SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 25G*1
12558SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 25G*5/8
12638SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 26G*3/8
12705SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 27G*1/2
12734SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 27G*3/4
12905SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 29G*1/2
13005SN	SOL-CARE Luer Lock Syringe with Safety Needle, 1ml, 30G*1/2
22010SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 20G*1
220125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 20G*1 1/4
22015SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 20G*1 1/2
22110SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 21G*1
221125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 21G*1 1/4
22115SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 22G*1 1/2
22210SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 22G*1
222125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 22G*1 1/4
22215SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 22G*1 1/2
22310SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 23G*1
223125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 23G*1 1/4
22315SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 23G*1 1/2
22510SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 25G*1
22558SN	SOL-CARE Luer Lock Syringe with Safety Needle, 2ml, 25G*5/8
32010SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 20G*1
32015SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 20G*1 1/2
32110SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 21G*1
32115SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 21G*1 1/2

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

32210SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 22G*1
32215SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 22G*1 1/2
32310SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 23G*1
32315SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 23G*1 1/2
323125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 23G*1 1/4
32410SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 24G*1"
324125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 24G*1 1/4"
32415SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 24G*1 1/2"
32510SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 25G*1
32558SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 25G*5/8
32515SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 25G*1 1/2"
52010SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 20G*1
52015SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 20G*1 1/2
52110SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 21G*1
52115SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 21G*1 1/2
52210SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 22G*1
52215SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 22G*1 1/2
523125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 23G*1 1/4
52410SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 24G*1"
524125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 24G*1 1/4"
52415SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 24G*1 1/2"
101815SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 18G*1 1/2"
102010SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 20G*1
102015SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 20G*1 1/2
102110SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 21G*1
102115SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 21G*1 1/2
102210SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 22G*1
102215SN	SOL-CARE Luer Lock Syringe with Safety Needle 10ml 22G*1 1/2
201815SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 18G*1 1/2"
1020125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 20G*1 1/4
2020125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 20G*1 1/4"
202015SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 20G*1 1/2"
202010SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 20G*1"
321125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 21G*1 1/4"
521125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 21G*1 1/4
1021125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 21G*1 1/4
2021125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 21G*1 1/4"
202115SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 21G*1 1/2"

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

202110SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 21G*1"
322125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 3ml, 22G*1 1/4"
522125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 22G*1 1/4"
1022125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 10ml, 22G*1 1/4"
2022125SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 22G*1 1/4"
202215SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 22G*1 1/2"
202210SN	SOL-CARE Luer Lock Syringe with Safety Needle, 20ml, 22G*1"
52315SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 23G*1 1/2"
52310SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 23G*1"
52558SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 25G*5/8"
52515SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 25G*1 1/2"
52510SN	SOL-CARE Luer Lock Syringe with Safety Needle, 5ml, 25G*1"

<b>Type/Model: Standard Luer Lock Syringe with Exchangeable Needle</b>	
<b>Basic UDI-DI: 081006243SN32YV</b>	
<b>REF number</b>	<b>Product name and Description</b>
18323125	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 23G*1 1/4"
18523125	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 23G*1 1/4"
1812010	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 20G*1"
1812015	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 20G*1 1/2"
1812110	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 21G*1"
1812115	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 21G*1 1/2"
1812210	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 22G*1"
1812310	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 23G*1"
1831815	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 18G*1 1/2"
1832010	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 20G*1"
1832015	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 20G*1 1/2"
1832110	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 21G*1"
1832115	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 21G*1 1/2"
1832210	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 22G*1"
18322125	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 22G*1 1/4"
1832215	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 22G*1 1/2"
1832310	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 23G*1"
1832510	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 25G*1"
1832515	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 25G*1 1/2"
1832558	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 25G*5/8"
1852010	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 20G*1"
1852015	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 20G*1 1/2"

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

1852110	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 21G*1
1852115	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 21G*1 1/2
1852210	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 22G*1
1852215	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 22G*1 1/2
1832315	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 23G*1 1/2
1832410	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 24G*1
18325125	SOL-M Luer Lock Syringe with Exchangeable Needle, 3ml, 25G*1 1/4
1851815	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 18G*1 1/2"
18522125	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 22G*1 1/4"
1852315	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 23G*1 1/2"
1852310	SOL-M Luer Lock Syringe with Exchangeable Needle, 5ml, 23G*1"
1811815	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 18G*1 1/2"
1812215	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 22G*1 1/2
18122125	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 22G*1 1/4
1812315	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 23G*1 1/2"
18123125	SOL-M Luer Lock Syringe with Exchangeable Needle, 10ml, 23G*1 1/4"
18202015	SOL-M Luer Lock Syringe with Exchangeable Needle, 20ml, 20G*1 1/2"
18201815	SOL-M Luer Lock Syringe with Exchangeable Needle, 20ml, 18G*1 1/2"
1852110T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 5ml, 21G*1
1832110T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 3ml, 21G*1
1852010T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 5ml, 20G*1
1832210T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 3ml, 22G*1
1832310T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 3ml, 23G*1
1832510T	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 3ml, 25G*1"
110101120011	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 10ml, 20G*1
110101120012	SOL-M Luer Lock Syringe with Exchangeable Needle Tray, 10ml, 21G*1

<b>Type/Model: Standard Luer Lock Syringe with Exchangeable Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243SN38Z9</b>	
<b>REF number</b>	<b>Product name and Description</b>
181023L	SOL-M Luer Lock Syringe with Exchangeable Needle, 1ml, 23G*1" (low dead space)
182023L	SOL-M Luer Lock Syringe with Exchangeable Needle, 1ml, 23G*1 1/2" (low dead space)
182025L	SOL-M Luer Lock Syringe with Exchangeable Needle, 1ml, 25G*1" (low dead space)
1810258L	SOL-M Luer Lock Syringe with Exchangeable Needle, 1ml, 25G*5/8" (low dead space)
1810215L	SOL-M Luer Lock Syringe with Exchangeable Needle, 1ml, 25G*1 1/2" (low dead space)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

<b>Generic device group</b>	Standard Luer Lock Syringe with Blunt Fill Needle
<b>EMDN code</b>	A020102020101
<b>Class</b>	Im+s
<b>Rule</b>	Rule 2
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	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.

<b>Type/Model: Standard Luer Lock Syringe with Blunt Fill Needle</b>	
<b>Basic UDI-DI: 081006243SN318TW</b>	
<b>REF number</b>	<b>Product name and Description</b>
1831810B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 3ml, 18G*1
1831815B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 3ml, 18G*1 1/2
1851810B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 5ml, 18G*1
1851815B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 5ml, 18G*1 1/2
1811810B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 10ml, 18G*1
1811815B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 10ml, 18G*1 1/2
1821810B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 20ml, 18G*1
1821815B	SOL-M Luer Lock Syringe with Blunt Fill Needle, 20ml, 18G*1 1/2
1831815BF	SOL-M Luer Lock Syringe with Blunt Fill Needle with Filter, 3ml, 18G*1 1/2"

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

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

<b>Type/Model: Standard Luer Lock Syringe without Needle</b>	
<b>Basic UDI-DI: 081006243SR318US</b>	
<b>REF number</b>	<b>Product name and Description</b>
180001	SOL-M Luer Lock Syringe without Needle, 1ml (PC)
180003	SOL-M Luer Lock Syringe without Needle, 3ml
180005	SOL-M Luer Lock Syringe without Needle, 5ml
180010	SOL-M Luer Lock Syringe without Needle, 10ml
180020	SOL-M Luer Lock Syringe without Needle, 20ml
180030	SOL-M Luer Lock Syringe without Needle, 30ml
P180050	SOL-M Luer Lock Syringe without Needle, 50ml
180060	SOL-M Luer Lock Syringe without Needle, 60ml
P180001PPBS	SOL-M Luer Lock Syringe without Needle, 1ml (PP) (bulk)
P180003BS	SOL-M Luer Lock Syringe without Needle, 3ml (bulk)
P180005BS	SOL-M Luer Lock Syringe without Needle, 5ml (bulk)
P180010BS	SOL-M Luer Lock Syringe without Needle, 10ml (bulk)
P180020BS	SOL-M Luer Lock Syringe without Needle, 20ml (bulk)
P180030BS	SOL-M Luer Lock Syringe without Needle, 30ml (bulk)
P180060BS	SOL-M Luer Lock Syringe without Needle, 60ml (bulk)
C180010BS	SOL-M Luer Lock Syringe without Needle, 10ml (bulk)
180001T	SOL-M Luer Lock Syringe Tray without Needle, 1ml (PP)
180001TPC	SOL-M Luer Lock Syringe Tray without Needle, 1ml (PC)
P180003T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 3ml
P180003TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 3ml
P180005T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 5ml
P180005TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 5ml
P180010T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 10ml
P180010TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 10ml
P180020T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 20ml
P180020TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 20ml
P180030T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 30ml
P180030TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 30ml
P180060T	SOL-M Luer Lock Syringe Sterile Convenience Tray, 60ml

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

P180060TU	SOL-M Luer Lock Syringe Sterile Convenience Tray, 60ml
-----------	--

<b>Type/Model: Standard Luer Lock Syringe without Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243SR313UG</b>	
<b>REF number</b>	<b>Product name and Description</b>
180001PP	SOL-M Luer Lock Syringe without Needle, 1ml (PP)
P180001PP	SOL-M Luer Lock Syringe without Needle, 1ml (PP)

<b>Generic device group</b>	Standard Luer Lock Syringe without Needle (suitable for use with power-driven syringe pumps)
<b>EMDN code</b>	A020102020102
<b>Class</b>	IIa
<b>Rule</b>	Rule 2
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	The Standard Luer Lock Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.

<b>Type/Model: Standard Luer Lock Syringe without Needle (suitable for use with power-driven syringe pumps)</b>	
<b>Basic UDI-DI: 081006243SR320UD</b>	
<b>REF number</b>	<b>Product name and Description</b>
P180001	SOL-M Luer Lock Syringe without Needle, 1ml (PP)
P180003	SOL-M Luer Lock Syringe without Needle, 3ml
P180005	SOL-M Luer Lock Syringe without Needle, 5ml
P180010	SOL-M Luer Lock Syringe without Needle, 10ml
P180020	SOL-M Luer Lock Syringe without Needle, 20ml
P180030	SOL-M Luer Lock Syringe without Needle, 30ml
P180060	SOL-M Luer Lock Syringe without Needle, 60ml

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

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

<b>Type/Model: Standard Syringe with Fixed Needle</b>	
<b>Basic UDI-DI: 081006243SN33YX</b>	
<b>REF number</b>	<b>Product name and Description</b>
405038	SOL-M Syringe with Needle, 1ml, 27G*1/2" (PE Bag, ALK)
405043	SOL-M Sterile Syringe Multi-Pack, 1ml 27G*1/2" (ALK)
181025T	SOL-M Syringe Tray, 1ml, 25G*5/8"
182025T	SOL-M Syringe Tray, 1ml, 25G*1"
181023T	SOL-M Mixing Syringe Tray, 1ml, 23G*1/2
181527T	SOL-M Allergy Syringe Tray, 0.5ml, 27G*3/8
180527T	SOL-M Allergy Syringe Tray, 0.5ml, 27G*1/2
181026T	SOL-M Allergy Syringe Tray, 1ml, 26G*1/2
181027T	SOL-M Allergy Syringe Tray, 1ml, 27G*1/2
181527IDBT	SOL-M Allergy Syringe Tray 0.5ml,, 27G*3/8 IDB
181026IDBT	SOL-M Allergy Syringe Tray, 1ml, 26G*3/8 IDB
181126IDBT	SOL-M Allergy Syringe Tray, 1ml, 26G*1/2 IDB
181027IDBT	SOL-M Allergy Syringe Tray, 1ml, 27G*3/8 IDB
SFN001	SOL-M Syringe with Fixed Needle, 0.3ml, 31G*6mm
180523	SOL-M Syringe with Fixed Needle, 0.5ml, 23G*1"
181525	SOL-M Syringe with Fixed Needle, 0.5ml, 25G 5/8"
180525	SOL-M Syringe with Fixed needle, 0.5ml, 25G 1"
181023	SOL-M Syringe with Fixed Needle, 1ml, 23G 1"
182025	SOL-M Syringe with Fixed Needle, 1ml, 25G*1
180527	SOL-M Syringe with Fixed Needle, 0.5ml, 27G*1/2
181025	SOL-M Syringe with Fixed Needle, 1ml ,25G*5/8
181026	SOL-M Syringe with Fixed Needle, 1ml, 26G*1/2
181027	SOL-M Syringe with Fixed Needle, 1ml, 27G*1/2
181026IDB	SOL-M Syringe with Fixed Needle, 1ml, 26G*3/8 IDB
181026B	SOL-M Syringe with Fixed Needle, 1ml, 26G*1/2" (PE bag)
181027B	SOL-M Syringe with Fixed Needle, 1ml, 27G*1/2" (PE bag)
181025B	SOL-M Syringe with Fixed Needle, 1ml, 25G*5/8" (PE bag)
181023B	SOL-M Syringe with Fixed Needle, 1ml, 23G*1/2" (PE bag)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

ATS001	SOL-M Syringe with Fixed Needle, 0.3ml, 31G*6mm (15/64"), (blister, sterile)
ATS002	SOL-M Syringe with Fixed Needle, 0.3ml, 31G*8mm (5/16"), (blister, sterile)
ATS003	SOL-M Syringe with Fixed Needle, 0.3ml, 31G*12.7mm (1/2"), (blister, sterile)
ATS004	SOL-M Syringe with Fixed Needle, 0.3ml, 32G*6mm (15/64"), (blister, sterile)
ATS005	SOL-M Syringe with Fixed Needle, 0.3ml, 32G*8mm (5/16"), (blister, sterile)
ATS006	SOL-M Syringe with Fixed Needle, 0.3ml, 32G*12.7mm (1/2"), (blister, sterile)
ATS007	SOL-M Syringe with Fixed Needle, 0.5ml, 31G*6mm (15/64"), (blister, sterile)
ATS008	SOL-M Syringe with Fixed Needle, 0.5ml, 31G*8mm (5/16"), (blister, sterile)
ATS009	SOL-M Syringe with Fixed Needle, 0.5ml, 31G*12.7mm (1/2"), (blister, sterile)
ATS010	SOL-M Syringe with Fixed Needle, 0.5ml, 32G*6mm (15/64"), (blister, sterile)
ATS011	SOL-M Syringe with Fixed Needle, 0.5ml, 32G*8mm (5/16"), (blister, sterile)
ATS012	SOL-M Syringe with Fixed Needle, 0.5ml, 32G*12.7mm (1/2"), (blister, sterile)
ATS013	SOL-M Syringe with Fixed Needle, 1ml, 31G*6mm (15/64"), (blister, sterile)
ATS014	SOL-M Syringe with Fixed Needle, 1ml, 31G*8mm (5/16"), (blister, sterile)
ATS015	SOL-M Syringe with Fixed Needle, 1ml, 31G*12.7mm (1/2"), (blister, sterile)
ATS016	SOL-M Syringe with Fixed Needle, 1ml, 32G*6mm (15/64"), (blister, sterile)
ATS017	SOL-M Syringe with Fixed Needle, 1ml, 32G*8mm (5/16"), (blister, sterile)
ATS018	SOL-M Syringe with Fixed Needle, 1ml, 32G*12.7mm (1/2"), (blister, sterile)
SSC365	SOL-M Syringe with Fixed Safety Needle, 1ml, 25G*1", (blister, sterile)
SSC366	SOL-M Syringe with Fixed Safety Needle, 1ml, 23G*1 1/2", (blister, sterile)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

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

<b>Type/Model: Insulin Standard Syringe with fixed needle Basic UDI-DI: 081006243INS1ZJ</b>	
<b>REF number</b>	<b>Product name and Description</b>
1632912B	SOL-M Insulin Syringe, 0.3ml, 29G*1/2 (PE Bag)
1633012B	SOL-M Insulin Syringe, 0.3ml, 30G*1/2 (PE Bag)
1633051B	SOL-M Insulin Syringe, 0.3ml, 30G*8mm (PE Bag)
1633151B	SOL-M Insulin Syringe, 0.3ml, 31G*8mm (PE Bag)
1652912B	SOL-M Insulin Syringe, 0.5ml, 29G*1/2 (PE Bag)
1653012B	SOL-M Insulin Syringe, 0.5ml, 30G*1/2 (PE Bag)
1653051B	SOL-M Insulin Syringe, 0.5ml, 30G*8mm (PE Bag)
1653151B	SOL-M Insulin Syringe, 0.5ml, 31G*8mm (PE Bag)
1612912B	SOL-M Insulin Syringe, 1ml, 29G*1/2 (PE Bag)
1613012B	SOL-M Insulin Syringe, 1ml, 30G*1/2 (PE Bag)
1613051B	SOL-M Insulin Syringe, 1ml, 30G*8mm (PE Bag)
1613151B	SOL-M Insulin Syringe, 1ml, 31G*8mm (PE Bag)
1612812B	SOL-M Insulin Syringe, 1ml, 28G*1/2 (PE Bag)
1612712B	SOL-M Insulin Syringe, 1ml, 27G*1/2 (PE Bag)
1612758B	SOL-M Insulin Syringe, 1ml, 27G*5/8 (PE Bag)
1652812B	SOL-M Insulin Syringe, 0.5ml, 28G*1/2 (PE Bag)
1652712B	SOL-M Insulin Syringe, 0.5ml, 27G*1/2 (PE Bag)
161311564B	SOL-M Insulin Syringe, 1ml, 31G*6mm (PE Bag)
163311564B	SOL-M Insulin Syringe, 0.3ml, 31Gx6mm (PE Bag) (1/2 unit marking)
165311564B	SOL-M Insulin Syringe, 0.5ml, 31Gx6mm (PE Bag) (1/2 unit marking)
163321564B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 32G*6mm(1/2 unit marking) (U-100 Insulin Only) (PE Bag)
1633251B	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 32G*8mm(1/2 unit marking) (U-100 Insulin Only) (PE Bag)
165321564B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 32G*6mm(1/2 unit marking) (U-100 Insulin Only) (PE Bag)
1653251B	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 32G*8mm(1/2 unit marking) (U-100 Insulin Only) (PE Bag)
161321564B	SOL-M 1ml Insulin Syringe w/Fixed Needle 32G*6mm(1 unit marking) (U-100 Insulin Only) (PE Bag)

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

1613251B	SOL-M 1ml Insulin Syringe w/Fixed Needle 32G*8mm(1 unit marking) (U-100 Insulin Only) (PE Bag)
163321564	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 32G*6mm(1/2 unit marking) (U-100 Insulin Only)
1633251	SOL-M 0.3ml Insulin Syringe w/Fixed Needle 32G*8mm(1/2 unit marking) (U-100 Insulin Only)
165321564	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 32G*6mm(1/2 unit marking) (U-100 Insulin Only)
1653251	SOL-M 0.5ml Insulin Syringe w/Fixed Needle 32G*8mm(1/2 unit marking) (U-100 Insulin Only)
161321564	SOL-M 1ml Insulin Syringe w/Fixed Needle 32G*6mm(1 unit marking) (U-100 Insulin Only)
1613251	SOL-M 1ml Insulin Syringe w/Fixed Needle 32G*8mm(1 unit marking) (U-100 Insulin Only)
1613051	SOL-M Insulin Syringe with Fixed Needle, 1ml, 30G*8mm
1653051	SOL-M Insulin Syringe with Fixed Needle, 0.5ml, 30G*8mm
1653151	SOL-M Insulin Syringe with Fixed Needle, 0.5ml, 31G*8mm (1/2 unit marking)
1613151	SOL-M Insulin Syringe with Fixed Needle, 1ml, 31G*8mm
1633051	SOL-M Insulin Syringe with Fixed Needle, 0.3ml, 30G*8mm
1652912	SOL-M Insulin Syringe with Fixed Needle, 0.5ml, 29G*1/2 (U-100 Insulin Only)
1612812	SOL-M Insulin Syringe with Fixed Needle, 1ml, 28G*1/2 (U-100 Insulin Only)
1612851	SOL-M Insulin Syringe with Fixed Needle, 1ml, 28G*5/16 (U-100 Insulin Only)
1612912	SOL-M Insulin Syringe with Fixed Needle, 1ml, 29G*1/2 (U-100 Insulin Only)
1613012	SOL-M Insulin Syringe with Fixed Needle, 1ml, 30G*1/2 (U-100 Insulin Only)
1612512	SOL-M Insulin Syringe with Fixed Needle, 1ml, 25G*1/2 (U-100 Insulin Only)
165311564	SOL-M Insulin Syringe with Fixed Needle, 0.5ml, 31G*6mm
161311564	SOL-M Insulin Syringe with Fixed Needle, 1ml, 31G*6mm

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

## EU Declaration of Conformity TF-05 rev.10

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

<b>Type/Model: Insulin Standard Syringe without Needle</b>	
<b>Basic UDI-DI: 081006243INS6ZU</b>	
<b>REF number</b>	<b>Product name and Description</b>
161000	SOL-M Slip Tip Insulin Syringe without Needle, 1ml
161000LL	SOL-M Insulin Syringe Luer Lock without Needle, 1ml

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

<b>Type/Model: Insulin Standard Syringe Slip Tip with Exchangeable Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243INS3ZN</b>	
<b>REF number</b>	<b>Product name and Description</b>
505040	SOL-M Insulin Syringe Slip Tip with Exchangeable Needle, 1ml, 30G*8mm, ALK
505039	SOL-M Insulin Syringe Slip Tip with Exchangeable Needle, 1ml, 30G*1/2, ALK
505038	SOL-M Insulin Syringe Slip Tip with Exchangeable Needle, 1ml, 29G*1/2, ALK
505037	SOL-M Insulin Syringe Slip Tip with Exchangeable Needle, 1ml, 25G*1, ALK

<b>Type/Model: Insulin Standard Syringe Slip Tip with Exchangeable Needle (low dead space)</b>	
<b>Basic UDI-DI: 081006243INS5ZS</b>	
<b>REF number</b>	<b>Product name and Description</b>
012558S	SOL-M Slip Tip Insulin Syringe with Exchangeable Needle, 1ml, 25G*5/8 (low dead space tip, orange plunger)
INS157	SOL-M Insulin Syringe Slip Tip with Exchangeable Needle, 1ml, 25G*1/2

<b>Type/Model: Insulin Standard Syringe Luer Lock with Safety Needle</b>	
<b>Basic UDI-DI: 081006243INS823</b>	
<b>REF number</b>	<b>Product name and Description</b>

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**  
311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097

**EU Declaration of Conformity  
TF-05 rev.10**

12905SNI	SOL-CARE Luer Lock Insulin Syringe with Safety Needle, 1ml, 29G*1/2
13005SNI	SOL-CARE Luer Lock Insulin Syringe with Safety Needle, 1ml, 30G*1/2

<b>Generic device group</b>	Syringe Tip Cap
<b>EMDN code</b>	A070599
<b>Class</b>	Is
<b>Rule</b>	Rule 1
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	Syringe Tip Cap is designed to cover the syringe tip to keep it clean when the syringe is not in use.

<b>Type/Model: Syringe Tip Cap</b>	
<b>Basic UDI-DI: 081006243ACC2UM</b>	
<b>REF number</b>	<b>Product name and Description</b>
STCB01	SOL-M Syringe Tip Cap, Blue
STCB02	SOL-M Syringe Tip Cap, Red
STCB01BS	SOL-M Syringe Tip Cap, Blue (Bulk, Sterile)
STCB02BS	SOL-M Syringe Tip Cap, Red (Bulk, Sterile)
STCT01	SOL-M Syringe Tip Cap Tray, Black

**-END of DOCUMENT-**

**GLOBAL CORPORATE HEADQUARTERS**

**Sol-Millennium Medical Inc.**

311 S. Wacker, Suite 4100,  
Chicago, IL 60606

Template-0097