

**EU Declaration of Conformity**  
**TF-04 rev.04**

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

<b>Manufacturer:</b>	SOL-Millennium Medical, Inc. 315 Shawnee North Drive, Suite 100 Suwanee, Georgia 30024, USA
<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-04
<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, 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.

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**Medical Device**  
**(Generic device group)**

- Safety Syringe with fixed needle (Shield Technology)
- Insulin Safety Syringe with fixed Needle (Shield Technology)

**Conformity Assessment Procedure**

Annex IX, Chapter I and III

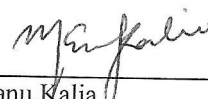
**Additional information**

Regulatory Affairs Contact Point:



[EMEA\\_ORA@sol-m.com](mailto:EMEA_ORA@sol-m.com)

Suwanee, Georgia 30024, USA,  
22 May 2023

  
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Manu Kalia  
Director, Quality Assurance  
PRRC

24-MAY-2023.

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**Attachment 1**

<b>Generic device group</b>	Safety Syringe with fixed needle (Shield Technology)
<b>EMDN code</b>	A02010205
<b>Class</b>	IIa
<b>Rule</b>	6
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	The Safety Syringe with fixed needle is used to inject fluids into, or withdraw fluids from, the body. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

<b>Type/Model: Safety Syringe with fixed needle</b>	
<b>Basic UDI-DI: 081006243SSG13G</b>	
<b>REF number</b>	<b>Description</b>
200018SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 25G*5/8
200019SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 27G*1/2
200034SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 25G*1
200035SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 23G*1
2102215SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 22G*1 1/2
200067SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 28G*1/2
2131516SG	SOL-GUARD 1ml TB Safety Syringe w/Fixed Needle 31G*8mm
2031516SG	SOL-GUARD 0.3ml TB Safety Syringe w/Fixed Needle 31G*8mm
200006SG	SOL-GUARD 0.5ml TB Safety Syringe w/Fixed Needle 23G*1
200007SG	SOL-GUARD 0.5ml TB Safety Syringe w/Fixed Needle 25G*1
200090SG	SOL-GUARD 0.5ml TB Safety Syringe w/Fixed Needle 27G*1/2
2051516SG	SOL-GUARD 0.5ml TB Safety Syringe w/Fixed Needle 31G*8mm
200088SG	SOL-GUARD 1ml Safety Syringe Flu Tray 25G*1
200032SG	SOL-GUARD 1ml Safety Syringe Allergy Tray 27G*1/2
200069SG	SOL-GUARD 1ml Safety Syringe Allergy Tray 26G*3/8 IDB
SSA001	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 26G*3/8"
SSA002	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 27G*1/2"
SSA003	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 31G*5/16"
SSA004	Sol-M 0.3ml Safety Shield Syringe w/Fixed Needle 31G*5/16"
SSA005	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 27G*1/2"
SSA006	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 31G*5/16"
SSA007	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 28G*1/2"
SSA009	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 25G*5/8"
SSA013	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 30G*1/2"
SSA015	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 26G*1/2"
SSA016	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 23G*3/8"

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SSA017	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 28G*1/2"
SSA018	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 25G*5/8"
SSA019	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 26G*3/8" IDB
SSA021	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 26G*1/2"
SSA023	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 27G*3/8" IDB
SSA024	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 29G*1/2"
SSA025	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 30G*1/2"
SSA026	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 27G*3/8" IDB
SSA008	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 25G*1"
SSA010	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 23G*1"
SSA011	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 23G*1"
SSA012	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 25G*1"
SSA039	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 26G*1/2" IDB
SSA040	Sol-M 0.5ml Safety Shield Syringe w/Fixed Needle 27G*1/2" IDB
SSA041	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 26G*3/8" IDB
SSA042	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 26G*1/2" IDB
SSA043	Sol-M 1ml Safety Shield Syringe w/Fixed Needle 27G*1/2" IDB

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<b>Generic device group</b>	Insulin Safety Syringe with Fixed Needle (Shield Technology)
<b>EMDN code</b>	A0201060301
<b>Class</b>	IIa
<b>Rule</b>	6
<b>Sterility</b>	Sterile, Single use
<b>Intended Purpose</b>	The Safety Syringe with fixed needle is used to inject Insulin into the body with the calibration units of U-100. In addition, the Safety Syringe is designed to aid in the prevention of needle stick injuries.

<b>Type/Model: Insulin Safety Syringe with Fixed Needle</b>	
<b>Basic UDI-DI: 081006243SIG1ZT</b>	
<b>REF number</b>	<b>Description</b>
200003SG	SOL-GUARD 0.3ml Insulin Safety Syringe w/Fixed Needle 29G*1/2
2331516SG	SOL-GUARD 0.3ml Insulin Safety Syringe w/Fixed Needle 31G*8mm
233068SG	SOL-GUARD 0.3ml Insulin Safety Syringe w/Fixed Needle 30G*6mm
233105SG	SOL-GUARD 0.3ml Insulin Safety Syringe w/Fixed Needle 31G*1/2
233165SG	SOL-GUARD 0.3ml Insulin Safety Syringe w/Fixed Needle 31G*6mm
2531516SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 31G*8mm
200002SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 29G*1/2
253068SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*6mm
253105SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 31G*1/2
253165SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 31G*6mm
2530516SG	SOL-GUARD 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*8mm
200091SG	SOL-GUARD 1ml Insulin Safety Syringe w/Fixed Needle 31G*8mm
200017SG	SOL-GUARD 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2
200092SG	SOL-GUARD 1ml Insulin Safety Syringe w/Fixed Needle 31G*1/2
200094SG	SOL-GUARD 1ml Insulin Safety Syringe w/Fixed Needle 30G*6mm
200093SG	SOL-GUARD 1ml Insulin Safety Syringe w/Fixed Needle 31G*6mm
SSI001	SOL-M 0.3ml Insulin Safety Syringe w/Fixed Needle 29Gx1/2"
SSI002	SOL-M 0.5ml Insulin Safety Syringe w/Fixed Needle 29G*1/2"
SSI003	SOL-M 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2"
SSI004	SOL-M 0.3ml Safety Insulin Syringe w/Fixed Needle 31Gx6mm
SSI005	SOL-M 0.5ml Safety Insulin Syringe w/Fixed Needle 31Gx6mm
SSI006	SOL-M 1ml Safety Insulin Syringe w/Fixed Needle 31Gx6mm
SSI007	SOL-M 0.3ml Safety Insulin Syringe w/Fixed Needle 31Gx8mm
SSI008	SOL-M 0.5ml Safety Insulin Syringe w/Fixed Needle 31Gx8mm
SSI009	SOL-M 1ml Safety Insulin Syringe w/Fixed Needle 31Gx8mm

-END of DOCUMENT-

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