

**EU Declaration of Conformity  
TF-03 rev.06**

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

**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

**Technical File reference:** TF-03

**Basic UDI-DI:** See Attachment 1

**Device Identification:** See Attachment 1

**Risk Class and Rule(s):** See Attachment 1

**Notified Body:** BSI Group The Netherlands B.V.  
Say Building  
John M. Keynesplein 9  
1066 EP, Amsterdam  
Netherlands  
Certificate number MDR 766495 R000

**Notified Body Number:** 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.

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## EU Declaration of Conformity TF-03 rev.06

**Medical Device  
(Generic device group)**

- Safety Syringe (Manual Retractable)
- Safety Insulin Syringe (Manual Retractable)

**Conformity Assessment Procedure**

Annex IX, Chapter I and III

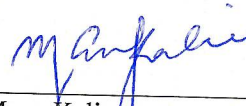
**Additional information**

Regulatory Affairs Contact Point:



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

Suwanee, Georgia 30024, USA,  
06/13/2023



Manu Kalia  
*Director, Quality Assurance  
PRRC*

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**Attachment 1**

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

<b>Type/Model: SOL-CARE Luer Lock Safety Syringe without Needle</b>	
<b>Basic UDI-DI: 081006243SSR24K</b>	
<b>REF number</b>	<b>Description</b>
120006IM	SOL-CARE 3ml Luer Lock Safety Syringe w/o Needle
120007IM	SOL-CARE 5ml Luer Lock Safety Syringe w/o Needle
120008IM	SOL-CARE 10ml Luer Lock Safety Syringe w/o Needle
120009IM	SOL-CARE 20ml Luer Lock Safety Syringe w/o Needle

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

<b>Type/Model: SOL-CARE Safety Syringe with Fixed Needle</b>	
<b>Basic UDI-DI: 081006243SSR64T</b>	
<b>REF number</b>	<b>Description</b>
SSR224	SOL-CARE 1ml Safety Syringe w/Fixed Needle 23G*1
SSR223	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*1 1/2"
100006IMPRO	SOL-CARE/PROMAMEC 0.5ml Safety Syringe w/Fixed Needle 23G*1

<b>Type/Model: SOL-CARE TB Safety Syringe with Fixed Needle</b>	
<b>Basic UDI-DI: 081006243SISR32F</b>	
<b>REF number</b>	<b>Description</b>
100006IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 23G*1
100007IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 25G*1
100008IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 26G*1/2
100090IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 27G*1/2
100009IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 27G*1
100010IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 30G*1/2
100023IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 23G*3/8
100082IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 30G*1/2
100018IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*5/8
100019IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 27G*1/2
100029IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 29G*1/2
100034IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 25G*1
100067IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 28G*1/2
100026IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 27G*3/8
100040IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 22G*1 1/2
100025IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 26G*1/2
100011IM	SOL-CARE 0.5ml Safety Syringe w/Fixed Needle 26G*3/8 IDB
100070IM	SOL-CARE 1ml Safety Syringe w/Fixed Needle 26G*3/8 IDB
104004	SOL-CARE/ALK 0.5ml Allergy Safety Syringe w/Fixed Needle 27G*1/2"

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<b>Type/Model: SOL-CARE TB Safety Syringe with Fixed Needle</b>	
<b>Basic UDI-DI: 081006243SISR32F</b>	
REF number	Description
105008	SOL-CARE/ALK 1ml Allergy Safety Syringe w/Fixed Needle 27G*1/2"
100088IM	SOL-CARE 1ml Safety Syringe Flu Tray 25G*1
100033IM	SOL-CARE 0.5ml Safety Syringe Allergy Tray 27G*1/2"
100035IM	SOL-CARE 0.5ml Safety Syringe Allergy Tray 26G*3/8" IDB
100032IM	SOL-CARE 1ml Safety Syringe Allergy Tray 27G*1/2"
100069IM	SOL-CARE 1ml Safety Syringe Allergy Tray 26G*3/8" IDB

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

<b>Type/Model: SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle</b>	
<b>Basic UDI-DI: 081006243SSR14H</b>	
REF number	Description
100059IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
100074IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 20G*1
100075IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1
100060IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/4"
100072IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
100085IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1
100076IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
100077IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1
100086IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 24G*1
100079IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1
100078IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*5/8
100099IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1 1/2"
100073IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/2"
100062IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4"
100064IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4"
100068IM	SOL-CARE 3ml Luer Lock Safety Syringe w/Exch Needle 25G*1 1/4"

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### TF-03 rev.06

140059IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
140072IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
140076IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
140086IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 24G*1
140084IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 20G*1
140075IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1
140060IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/4
140085IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1
140062IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4
140077IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1
140065IM	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4
SSR231	SOL-CARE 5ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/2
160072IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
160059IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
160074IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 20G*1
160084IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 20G*1 1/2
160075IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 21G*1
160062IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/4
160076IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1 1/2
160065IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 23G*1 1/4
160077IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 23G*1
160085IM	SOL-CARE 10ml Luer Lock Safety Syringe w/Exch Needle 22G*1
190072IM	SOL-CARE 20ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
190059IM	SOL-CARE 20ml Luer Lock Safety Syringe w/Exch Needle 18G*1 1/2
100072IMPRO	SOL-CARE/PROMAMEC 3ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
140072IMPRO	SOL-CARE/PROMAMEC 5ml Luer Lock Safety Syringe w/Exch Needle 21G*1 1/2
160072IMPRO	SOL-CARE/PROMAMEC 10ml Luer Lock Safety Syringe with Exchangeable Needle 21G*1 1/2
190072IMPRO	SOL-CARE/PROMAMEC 20ml Luer Lock Safety Syringe with Exchangeable Needle 21G*1 1/2

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

<b>Type/Model: SOL-CARE Insulin Safety Syringe with Fixed Needle Basic UDI-DI: 081006243SIS132</b>	
<b>REF number</b>	<b>Description</b>
100001IM	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*1/2 (U-100 Insulin Only)
100002IM	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 29G*1/2 (U-100 Insulin Only)
100089IM	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*8mm (U-100 Insulin Only)
100095IM	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 30G*6mm (U-100 Insulin Only)
100017IM	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2 (U-100 Insulin Only)
100081IM	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*1/2 (U-100 Insulin Only)
100020IM	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*8mm (U-100 Insulin Only)
100071IM	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 28G*1/2 (U-100 Insulin Only)
100094IM	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 30G*6mm (U-100 Insulin Only)
100017IMPRO	SOL-CARE/PROMAMEC 1ml Insulin Safety Syringe w/Fixed Needle 29G*1/2" (U-100 Insulin Only)

<b>Type/Model: SOL-CARE Insulin Safety Syringe with Fixed Needle (U-100 Insulin Only) Basic UDI-DI: 081006243SIS234</b>	
<b>REF number</b>	<b>Description</b>
SIS056	SOL-CARE 1ml Insulin Safety Syringe w/Fixed Needle 31G*6mm (U-100 Insulin Only)
SIS055	SOL-CARE 0.5ml Insulin Safety Syringe w/Fixed Needle 31G*6mm (U-100 Insulin Only)

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