Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

Annex IV of Regulation (EU) 2017/745

Manufacturer:	SOL-Millennium Medical, Inc. 311 S Wacker Drive, Suite 4100 Chicago, Illinois, 60606, UNITED STATES
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.

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

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

Chicago, Illinois, 60606, UNITED STATES

DocuSigned by:
2CF5274F177E4F6...
3-Sep-2024

Manu Kalia
Senior Director, QARA
PRRC

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

Attachment 1

Generic device group:	**Safety Syringe (Manual Retractable)**
EMDN code	**A02010205**
Class	**Is+m**
Rule	**2**
Sterility	**Sterile**
Intended Purpose	**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.**

Type/Model: SOL-CARE Luer Lock Safety Syringe without Needle **Basic UDI-DI: 081006243SSR24K**	
REF number	**Product name and description**
120006IM	SOL-CARE Luer Lock Safety Syringe without Needle, 3 ml
120007IM	SOL-CARE Luer Lock Safety Syringe without Needle, 5 ml
120008IM	SOL-CARE Luer Lock Safety Syringe without Needle, 10 ml
120009IM	SOL-CARE Luer Lock Safety Syringe without Needle, 20 ml

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

Generic device group:	**Safety Syringe (Manual Retractable)**
EMDN code	**A02010204**
Class	**IIa**
Rule	**6**
Sterility	**Sterile**
Intended use	**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.**

Type/Model: SOL-CARE Safety Syringe with Fixed Needle **Basic UDI-DI: 081006243SSR64T**	
REF number	**Product name and description**
SSR224	SOL-CARE Safety Syringe with Fixed Needle , 1ml, 23G*1
SSR223	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 25G*1 1/2"
100006IMPRO	SOL-CARE Safety Syringe with Fixed Needle, 0.5 ml, 23G*1

Type/Model: SOL-CARE TB Safety Syringe with Fixed Needle **Basic UDI-DI: 081006243SISR32F**	
REF number	**Product name and description**
100006IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5 ml, 23G*1
100007IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5 ml, 25G*1
100008IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5 ml, 26G*1/2
100090IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5ml, 27G*1/2
100009IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5ml, 27G*1
100010IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5ml, 30G*1/2
100023IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5ml, 23G*3/8
100082IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 30G*1/2
100018IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 25G*5/8
100019IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 27G*1/2
100029IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 29G*1/2
100034IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 25G*1
100067IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 28G*1/2
100026IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 27G*3/8
100040IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 22G*1 1/2
100025IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 26G*1/2
100011IM	SOL-CARE Safety Syringe with Fixed Needle, 0.5ml, 26G*3/8 IDB
100070IM	SOL-CARE Safety Syringe with Fixed Needle, 1ml, 26G*3/8 IDB
104004	SOL-CARE Allergy Safety Syringe with Fixed Needle, 0.5ml, 27G*1/2"
105008	SOL-CARE Allergy Safety Syringe, 1ml, 27G*1/2"
100088IM	SOL-CARE Safety Syringe Flu Tray, 1ml, 25G*1

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

Type/Model: SOL-CARE TB Safety Syringe with Fixed Needle **Basic UDI-DI: 081006243SISR32F**	
REF number	**Product name and description**
100033IM	SOL-CARE Safety Syringe Allergy Tray, 0.5 ml, 27G*1/2"
100035IM	SOL-CARE Safety Syringe Allergy Tray, 0.5 ml, 26G*3/8" IDB
100032IM	SOL-CARE Safety Syringe Allergy Tray, 1 ml, 27G*1/2"
100069IM	SOL-CARE Safety Syringe Allergy Tray, 1 ml, 26G*3/8" IDB

Generic device group:	**Safety Syringe (Manual Retractable)**
EMDN code	**A02010205**
Class	**IIa**
Rule	**6**
Sterility	**Sterile**
Intended use	**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.**

Type/Model: SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle **Basic UDI-DI: 081006243SSR14H**	
REF number	**Product name and description**
100059IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml 18G*1 1/2
100074IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 20G*1
100084IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 20G*1 1/2
100075IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 21G*1
100060IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 21G*1 1/4"
100072IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 21G*1 1/2
100085IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 22G*1
100076IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 22G*1 1/2
100077IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 23G*1
100086IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 24G*1
100079IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 25G*1
100078IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 25G*5/8
100099IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 25G*1 1/2"
100073IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 23G*1 1/2"
100062IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 22G*1 1/4"
100064IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 23G*1 1/4"
100068IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle,3ml, 25G*1 1/4"
140059IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 18G*1 1/2
140072IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 21G*1 1/2

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

EU Declaration of Conformity
TF-03 rev.07

140076IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 22G*1 1/2
140086IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 24G*1
140084IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 20G*1
140075IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 21G*1
140060IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 21G*1 1/4
140085IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 22G*1
140062IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 22G*1 1/4
140077IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 23G*1
140065IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 23G*1 1/4
SSR231	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 23G*1 1/2
160072IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 21G*1 1/2
160059IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 18G*1 1/2
160074IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 20G*1
160084IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 20G*1 1/2
160075IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 21G*1
160062IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 22G*1 1/4
160076IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 22G*1 1/2
160065IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 23G*1 1/4
160077IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 23G*1
160085IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 22G*1
190072IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 20ml, 21G*1 1/2
190059IM	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 20ml, 18G*1 1/2
100072IMPRO	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 3ml, 21G*1 ½
140072IMPRO	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 5ml, 21G*1 1/2
160072IMPRO	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 10ml, 21G*1 1/2
190072IMPRO	SOL-CARE Luer Lock Safety Syringe with Exchangeable Needle, 20ml, 21G*1 1/2

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com

Docusign Envelope ID: C486D07D-8AB2-4B46-B8E2-FD6ED73F0F78

Sol M Building a Healthier Tomorrow

EU Declaration of Conformity
TF-03 rev.07

Generic device group	**Safety Insulin Syringe (Manual Retractable)**
EMDN code	**A02010603 (A02010204)**
Class	**IIa**
Rule	**6**
Sterility	**Sterile**
Intended use	**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.**

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

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

-END of DOCUMENT-

GLOBAL CORPORATE HEADQUARTERS
Sol-Millennium Medical Inc.
311 S. Wacker, Suite 4100,
Chicago, IL 60606

+1-833-637-0857
info@solm.com
www.solm.com