

EU Declaration of Conformity TF-07 rev.06

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-07
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 R001
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,
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Medical Device (Generic device group)

- Standard Blood Collection/Infusion Butterfly Needles
- Safety Blood Collection/Infusion Butterfly Needles
- Safety Blood Collection/Infusion Butterfly Needles with Holder
- Safety Pull-Button Blood Collection/Infusion Set
- Safety Pull-Button Blood Collection Set
- Blood Collection Luer Adapter
- Blood Collection Holder
- Blood Transfer Holder

Conformity Assessment Procedure

Annex IX, Chapter I and III

Additional information

Regulatory Affairs Contact Point:



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Chicago, Illinois, 60606, UNITED STATES

Signed by:
Edward Roles
 Signer Name: Edward Roles
Signing Reason: I approve this document
Signing Time: 6/19/2026 10:04:23 AM PDT
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Edward Roles
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Attachment 1

Generic device group	Standard Blood Collection/Infusion Butterfly Needles
EMDN code	A010102
Class	IIa
Rule	7
Sterility	Sterile, Single use
Intended Purpose	The Butterfly Needle is used for blood collection or/and short-term infusion of intravenous fluids

Type/Model: Standard Blood Collection/Infusion Butterfly Needles with Adapter Basic UDI-DI: 081006243BCN1VT	
REF number	Description
BCN213407	SOL-M Butterfly needle with Adapter 21G*3/4*7inch
BCN233407	SOL-M Butterfly needle with Adapter 23G*3/4*7inch
BCN253407	SOL-M Butterfly needle with Adapter 25G*3/4*7inch
BCN213412	SOL-M Butterfly needle with Adapter 21G*3/4*12inch
BCN233412	SOL-M Butterfly needle with Adapter 23G*3/4*12inch
BCN253412	SOL-M Butterfly needle with Adapter 25G*3/4*12inch

Type/Model: Standard Blood Collection/Infusion Butterfly Needles with Luer Cap Basic UDI-DI: 081006243BCN1VT	
REF number	Description
WIS213407	SOL-M Butterfly needle with End Luer Cap 21G*3/4*7inch
WIS233407	SOL-M Butterfly needle with End Luer Cap 23G*3/4*7inch
WIS253407	SOL-M Butterfly needle with End Luer Cap 25G*3/4*7inch
WIS213412	SOL-M Butterfly needle with End Luer Cap 21G*3/4*12inch
WIS233412	SOL-M Butterfly needle with End Luer Cap 23G*3/4*12inch
WIS253412	SOL-M Butterfly needle with End Luer Cap 25G*3/4*12inch

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Generic device group	Safety Blood Collection/Infusion Butterfly Needles
EMDN code	A01010201
Class	IIa
Rule	7
Sterility	Sterile, Single use
Intended Purpose	The Butterfly Needle is used for blood collection or/and short-term infusion of intravenous fluids

Type/Model: Safety Blood Collection/Infusion Butterfly Needles with Adapter	
Basic UDI-DI: 081006243SBC1YC	
REF number	Description
110201030003	SOL-CARE Safety Blood Collection Needle 21G*3/4*7inch
110201030007	SOL-CARE Safety Blood Collection Needle 23G*3/4*7inch
110201030011	SOL-CARE Safety Blood Collection Needle 25G*3/4*7inch
110201030015	SOL-CARE Safety Blood Collection Needle 21G*3/4*12inch
110201030017	SOL-CARE Safety Blood Collection Needle 21G*3/4*7inch
110201030019	SOL-CARE Safety Blood Collection Needle 23G*3/4*12inch
110201030021	SOL-CARE Safety Blood Collection Needle 23G*3/4*7inch
110201030023	SOL-CARE Safety Blood Collection Needle 25G*3/4*12inch
110201030025	SOL-CARE Safety Blood Collection Needle 25G*3/4*7inch
110201030027	SOL-CARE Safety Blood Collection Needle 19G*3/4*12inch
110201030030	SOL-CARE Safety Blood Collection Needle 21G*3/4*7inch
110201030030T	SOL-CARE Safety Blood Collection Needle 21G*3/4*7inch
110201030032	SOL-CARE Safety Blood Collection Needle 23G*3/4*7inch
110201030032T	SOL-CARE Safety Blood Collection Needle 23G*3/4*7inch
110201030001	SOL-CARE Safety Blood Collection Needle 21G*3/4*12inch
110201030031T	SOL-CARE Safety Blood Collection Needle 21G*3/4*12inch
110201030036	SOL-CARE Safety Blood Collection Needle 22G*3/4" 7inch
110201030036T	SOL-CARE Safety Blood Collection Needle 22G*3/4" 7inch
110201030034	SOL-CARE Safety Blood Collection Needle 25G*3/4*7inch
110201030034T	SOL-CARE Safety Blood Collection Needle 25G*3/4*7inch
110201030029	SOL-CARE Safety Blood Collection Needle 19G*3/4*12inch
110201030031	SOL-CARE Safety Blood Collection Needle 21G*3/4*12inch
110201030033	SOL-CARE Safety Blood Collection Needle 23G*3/4*12inch
110201030033T	SOL-CARE Safety Blood Collection Needle 23G*3/4*12inch
110201030035	SOL-CARE Safety Blood Collection Needle 25G*3/4*12inch
110201030035T	SOL-CARE Safety Blood Collection Needle 25G*3/4*12inch
110201030037	SOL-CARE Safety Blood Collection Needle 22G*3/4" 12inch
110201030037T	SOL-CARE Safety Blood Collection Needle 22G*3/4" 12inch
110201030005	SOL-CARE Safety Blood Collection Needle 23G*3/4*12inch
110201030009	SOL-CARE Safety Blood Collection Needle 25G*3/4*12inch
SBCNS2507	SOL-CARE Safety Blood Collection Needle Softpack 25G*3/4*7inch
SBCNS2512	SOL-CARE Safety Blood Collection Needle Softpack 25G*3/4*12inch
SBCNS2307	SOL-CARE Safety Blood Collection Needle Softpack 23G*3/4*7inch

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SBCNS2312	SOL-CARE Safety Blood Collection Needle Softpack 23G*3/4*12inch
SBCNS2207	SOL-CARE Safety Blood Collection Needle Softpack 22G*3/4" 7inch
SBCNS2212	SOL-CARE Safety Blood Collection Needle Softpack 22G*3/4" 12inch
SBCNS2107	SOL-CARE Safety Blood Collection Needle Softpack 21G*3/4*7inch
SBCNS2112	SOL-CARE Safety Blood Collection Needle Softpack 21G*3/4*12inch
SBCNS1907	SOL-CARE Safety Blood Collection Needle Softpack 19G*3/4*7inch
SBCNS1912	SOL-CARE Safety Blood Collection Needle Softpack 19G*3/4*12inch

Type/Model: Safety Blood Collection/Infusion Butterfly Needles with Luer Cap Basic UDI-DI: 081006243SBC1YC	
REF number	Description
193407SI	SOL-CARE Safety Winged Infusion Set 19G*3/4*7inch
213407SI	SOL-CARE Safety Winged Infusion Set 21G*3/4*7inch
223407SI	SOL-CARE Safety Winged Infusion Set 22G*3/4*7inch
233407SI	SOL-CARE Safety Winged Infusion Set 23G*3/4*7inch
253407SI	SOL-CARE Safety Winged Infusion Set 25G*3/4*7inch
193412SI	SOL-CARE Safety Winged Infusion Set 19G*3/4*12inch
213412SI	SOL-CARE Safety Winged Infusion Set 21G*3/4*12inch
223412SI	SOL-CARE Safety Winged Infusion Set 22G*3/4*12inch
233412SI	SOL-CARE Safety Winged Infusion Set 23G*3/4*12inch
253412SI	SOL-CARE Safety Winged Infusion Set 25G*3/4*12inch
S213407SI	SOL-CARE Safety Winged Infusion Set 21G*3/4*7inch softpack
S213412SI	SOL-CARE Safety Winged Infusion Set 21G*3/4*12inch softpack
S223407SI	SOL-CARE Safety Winged Infusion Set 22G*3/4*7inch softpack
S223412SI	SOL-CARE Safety Winged Infusion Set 22G*3/4*12inch softpack
S233407SI	SOL-CARE Safety Winged Infusion Set 23G*3/4*7inch softpack
S233412SI	SOL-CARE Safety Winged Infusion Set 23G*3/4*12inch softpack
S253407SI	SOL-CARE Safety Winged Infusion Set 25G*3/4*7inch softpack
S253412SI	SOL-CARE Safety Winged Infusion Set 25G*3/4*12inch softpack
S193412SI	SOL-CARE Safety Winged Infusion Set 19G*3/4*12inch softpack
S193407SI	SOL-CARE Safety Winged Infusion Set 19G*3/4*7inch softpack

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Generic device group	Safety Blood Collection/Infusion Butterfly Needles with Holder
EMDN code	A01010201
Class	IIa
Rule	6
Sterility	Sterile, Single use
Intended Purpose	The Butterfly Needle with pre-attached holder is used for blood collection (when used with the Holder with Male Luer Adapter accessory)

Type/Model: Safety Blood Collection/Infusion Butterfly Needles with Holder	
Basic UDI-DI: 081006243SBC1YC	
REF number	Description
110201030004	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*7inch
110201030004T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*7inch
110201030008	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*7inch
110201030008T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*7inch
110201030012	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*7inch
110201030012T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*7inch
110201030016	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*12inch
110201030018	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*7inch
110201030020	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*12inch
110201030022	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*7inch
110201030024	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*12inch
110201030026	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*7inch
110201030028	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 19G*3/4*12inch
110201030002	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*12inch
110201030002T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*12inch
110201030006	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*12inch
110201030006T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*12inch
110201030010	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*12inch
110201030010T	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*12inch
SBCNHS2112	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*12inch
SBCNHS2507	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*7inch
SBCNHS2512	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*12inch
SBCNHS2307	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*7inch
SBCNHS2312	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 23G*3/4*12inch
SBCNHS2107	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 21G*3/4*7inch

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Generic device group	Safety Pull-Button Blood Collection/Infusion Set
EMDN code	A01010201
Class	IIa
Rule	7
Sterility	Sterile, Single use
Intended Purpose	The Safety Pull-Button Blood Collection/Infusion Set is used for short-term infusion of intravenous fluids or blood collection

Type/Model: Safety Pull-button Infusion Set with Cap Basic UDI-DI: 081006243SPB12J	
REF number	Description
PBNL2112	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 21G*3/4*12inch
PBNL2312	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 23G*3/4*12inch
PBNL2512	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 23G*3/4*12inch
PBNL2107	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 21G*3/4*7inch
PBNL2307	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 23G*3/4*7inch
PBNL2507	SOL-GUARD XtraThin Safety Pull-button IV Infusion Set 25G*3/4*7inch
PBIV2107	SOL-GUARD Safety Pull-button IV Infusion Set 21G*3/4*7inch
PBIV2307	SOL-GUARD Safety Pull-button IV Infusion Set 23G*3/4*7inch
PBIV2507	SOL-GUARD Safety Pull-button IV Infusion Set 25G*3/4*7inch
PBIV21012	SOL-GUARD Safety Pull-button IV Infusion Set 21G*3/4*12inch
PBIV23012	SOL-GUARD Safety Pull-button IV Infusion Set 23G*3/4*12inch
PBIV25012	SOL-GUARD Safety Pull-button IV Infusion Set 25G*3/4*12inch

Type/Model: Safety Pull-Button Blood Collection Set with Luer Adapter Basic UDI-DI: 081006243SPB12J	
REF number	Description
PBLA2107	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 21G*3/4*7inch
PBLA2112	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 21G*3/4*12inch
PBLA2307	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 23G*3/4*7inch
PBLA2312	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 23G*3/4*12inch
PBLA2507	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 25G*3/4*7inch
PBLA2512	SOL-GUARD Safety Pull-button Blood Collection Set with Luer Adapter, 25G*3/4*12inch
PBFLA2112	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with luer adapter 21G*3/4*12inch
PBFLA2112T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 21G*3/4*12inch

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PBFLA2312	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 23G*3/4*12inch
PBFLA2312T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 23G*3/4*12inch
PBFLA2512	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 25G*3/4*12inch
PBFLA2512T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 25G*3/4*12inch
PBFLA2107	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 21G*3/4*7inch
PBFLA2107T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 21G*3/4*7inch
PBFLA2307	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 23G*3/4*7inch
PBFLA2307T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 23G*3/4*7inch
PBFLA2507	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 25G*3/4*7inch
PBFLA2507T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Luer Adapter, 25G*3/4*7inch

Generic device group	Safety Pull-Button Blood Collection Set
EMDN code	A01010201
Class	IIa
Rule	6
Sterility	Sterile, Single use
Intended Purpose	The Safety Pull-Button Blood Collection Set is used for blood collection when used with the Holder

Type/Model: Safety Pull-Button Blood Collection Set with Holder	
Basic UDI-DI: 081006243SPB12J	
REF number	Description
PBH2107	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 21G*3/4*7inch
PBH2112	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 21G*3/4*12inch
PBH2307	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 23G*3/4*7inch
PBH2312	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 23G*3/4*12inch
PBH2507	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 25G*3/4*7inch

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PBH2512	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 25G*3/4*12inch
PBFH2112	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 21G*3/4 12inch
PBFH2112T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 21G*3/4 12inch
PBFH2512	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 25G*3/4 12inch
PBFH2512T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 25G*3/4 12inch
PBFH2312	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 23G*3/4 12inch
PBFH2312T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 23G*3/4 12inch
PBFH2107	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 21G*3/4*7inch
PBFH2107T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 21G*3/4*7inch
PBFH2507	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 25G*3/4*7inch
PBFH2507T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 25G*3/4*7inch
PBFH2307	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 23G*3/4*7inch
PBFH2307T	SOL-GUARD XtraThin Safety Pull-Button Blood Collection Set with Pre-attached Holder 23G*3/4*7inch

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Generic device group	Blood Collection Luer Adapter
EMDN code	A010180
Class	Is
Rule	1
Sterility	Sterile, Single use
Intended Purpose	The Luer Adapter is noninvasive device used to connect venous access devices including blood collection sets, winged infusion sets to blood collection tubes. and non-needle devices for collection of blood specimens.

Type/Model: Blood Collection Luer Adapter Basic UDI-DI: 081006243BCA3UQ	
REF number	Description
LA21920	SOL-M Luer Adapter

Generic device group	Blood Collection Holder
EMDN code	A010180
Class	Is
Rule	1
Sterility	Sterile, Single use
Intended Purpose	The Tube Holder with Luer Lock Adapter is a sterile noninvasive device used to connect venous access devices including blood collection sets, winged infusion sets to blood collection tubes and non-needle devices for collection of blood specimens.

Type/Model: Blood Collection Holder Basic UDI-DI: 081006243BCA2UN	
REF number	Description
110201050003	SOL-M Tube Holder with Luer Lock Adapter

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Generic device group	Blood Transfer Holder
EMDN code	A0380
Class	Is
Rule	1
Sterility	Sterile, Single use
Intended Purpose	The Blood Transfer Holder is a sterile noninvasive device intended to transfer blood specimen to a blood collection tube or blood culture bottle.

Type/Model: Blood Transfer Holder	
Basic UDI-DI: 081006243BCA4US	
REF number	Description
BCTH002	SOL-M Blood Transfer Holder

-END of DOCUMENT-

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