

EU Declaration of Conformity TF-07 rev.00

Annex II of Council Directive 93/42/EEC

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-07
Basic UDI-DI:	See Attachment 1
Device Identification:	See Attachment 1
Risk Class and Rule(s):	See Attachment 1
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany Certificate number G1.098579.0004. Rev. 00
Notified Body Number:	0123

Declaration Statement:

We herewith declare that the medical devices listed in attachment 1 meet the provisions of Annex II excluding p.4) of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices with amendments and the provisions of the Article 120 p. 3 of the 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. The Manufacturer confirms that there are no significant changes in the design and intended purpose for the devices covered by this Declaration of Conformity and the requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are apply in place of the corresponding requirements in Regulation (EU) 2017/745.

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

GLOBAL CORPORATE HEADQUARTERS

Sol-Millennium Medical Inc.

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EU Declaration of Conformity TF-07 rev.00

Medical Device (Generic device group)

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

Conformity Assessment Procedure

Annex II excluding p.4)

Additional information

Regulatory Affairs Contact Point:



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Suwanee, Georgia 30024, USA,

8/22/2023

M/DD/YYYY

DocuSigned by:

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Manu Kalia
Director-QA

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EU Declaration of Conformity TF-07 rev.00

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
551066	Samplix® Blood Collection Set + Luer Adapter 21G*3/4" *7inch
551089	Samplix® Blood Collection Set + Luer Adapter 23G*3/4" *7inch
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
551155	Samplix Blood Collection/Infusion Set 23G*3/4*7inch
551153	Samplix Blood Collection/Infusion Set 21G*3/4*7inch

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EU Declaration of Conformity TF-07 rev.00

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: 081006243BC1YC	
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
110201030030	SOL-CARE Safety Blood Collection Needle 21G*3/4*7inch
110201030032	SOL-CARE Safety Blood Collection Needle 23G*3/4*7inch
110201030001	SOL-CARE Safety Blood Collection Needle 21G*3/4*12inch
110201030036	SOL-CARE Safety Blood Collection Needle 22G*3/4" 7inch
110201030034	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 19G*3/4*12inch
110201030033	SOL-CARE Safety Blood Collection Needle 23G*3/4*12inch
110201030035	SOL-CARE Safety Blood Collection Needle 25G*3/4*12inch
110201030037	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
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
45701	Vacumed Safety Blood Collection Needle 21G*3/4*7inch
45703	Vacumed Safety Blood Collection Needle 23G*3/4*7inch
451081	VACUETTE Safety Winged Set+Luer Adapter 21G*3/4*7inch
451082	VACUETTE Safety Winged Set+Luer Adapter 23G*3/4*7inch
451090	VACUETTE Safety Winged Set+Luer Adapter 25G*3/4*7inch
451095	VACUETTE Safety Winged Set+Luer Adapter 21G*3/4*12inch

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EU Declaration of Conformity

TF-07 rev.00

451096	VACUETTE Safety Winged Set+Luer Adapter 23G*3/4*12inch
451099	VACUETTE Safety Winged Set+Luer Adapter 25G*3/4*12inch
Type/Model: Safety Blood Collection/Infusion Butterfly Needles with Luer Cap	
Basic UDI-DI: 081006243BC1YC	
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
451091	VACUETTE Safety Winged Blood Collection/Infusion Set 21G*3/4*7inch
451092	VACUETTE Safety Winged Blood Collection/Infusion Set 23G*3/4*7inch

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EU Declaration of Conformity TF-07 rev.00

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: 081006243BC1YC	
REF number	Description
110201030004	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
110201030012	SOL-CARE Safety Blood Collection Needle w/Pre-attached Holder 25G*3/4*7inch
110201030002	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
110201030010	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
45711	Vacumed Safety Blood Collection Needle with Pre-attached Holder 21G*3/4*7inch
45713	Vacumed Safety Blood Collection Needle with Pre-attached Holder 23G*3/4*7inch
451161	VACUETTE Safety Winged Set+Holder 23G*3/4*12inch
451160	VACUETTE Safety Winged Set+Holder 21G*3/4*12inch
451086	VACUETTE Safety Winged Set+Holder 23G*3/4*7inch
451085	VACUETTE Safety Winged Set+Holder 21G*3/4*7inch

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EU Declaration of Conformity

TF-07 rev.00

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: 081006243SPB12	
REF number	Description
PBNL2112	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 21G*3/4*12inch
PBNL2312	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 23G*3/4*12inch
PBNL2512	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 25G*3/4*12inch
PBNL2107	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 21G*3/4*7inch
PBNL2307	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 23G*3/4*7inch
PBNL2507	SOL-GUARD Safety Pull-button IV Infusion Set w/ Ultra-thin Wall Needle 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: 081006243SPB12	
REF number	Description
PBLA2107	SOL-GUARD Safety Pull-button Blood Collection Set 21G*3/4*7inch
PBLA2112	SOL-GUARD Safety Pull-button Blood Collection Set 21G*3/4*12inch
PBLA2307	SOL-GUARD Safety Pull-button Blood Collection Set 23G*3/4*7inch
PBLA2312	SOL-GUARD Safety Pull-button Blood Collection Set 23G*3/4*12inch
PBLA2507	SOL-GUARD Safety Pull-button Blood Collection Set 25G*3/4*7inch
PBLA2512	SOL-GUARD Safety Pull-button Blood Collection Set 25G*3/4*12inch
PBFLA2112	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 21G*3/4*12inch
PBFLA2312	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 23G*3/4*12inch
PBFLA2512	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 25G*3/4*12inch
PBFLA2107	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 21G*3/4*7inch
PBFLA2307	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 23G*3/4*7inch
PBFLA2507	Sol-Guard Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle 25G*3/4*7inch

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EU Declaration of Conformity TF-07 rev.00

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: 081006243SPB12	
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
PBH2512	SOL-GUARD Safety Pull-button Blood Collection Set with Pre-attached Holder 25G*3/4*12inch
PBFH2112	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 21G*3/4 12inch
PBFH2512	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 25G*3/4 12inch
PBFH2312	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 23G*3/4 12inch
PBFH2107	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 21G*3/4*7inch
PBFH2507	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 25G*3/4*7inch
PBFH2307	SOL-GUARD Safety Pull-Button Blood Collection Set w/ Ultra-thin Wall Needle & Pre-attached Holder 23G*3/4*7in

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EU Declaration of Conformity

TF-07 rev.00

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
45200	Vacumed Luer Adapter
551070	Samplix 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. 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 Collection Holder Basic UDI-DI: 081006243BCA2UN	
REF number	Description
110201050003	SOL-M Tube Holder with Luer Lock Adapter
BCTH002	SOL-M Blood Transfer Holder

-END of DOCUMENT-

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