



EU Declaration of Conformity TF-08 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-08
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.

311 S. Wacker, Suite 4100,
Chicago, IL 60606



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**Medical Device
(Generic device group)**

Multi Sample Needle
Safety Multi Sample Needle 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-Aug-2023

DocuSigned by:

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Generic device group	Multi Sample Needle
EMDN code	A010199
Class	IIa
Rule	6
Sterility	Sterile, Single use
Intended Purpose	Multi Sample Needle is intended to be used with Needle holder as a system in routine venepuncture/blood collection procedure.

Type/Model: Multi Sample Needle	
Basic UDI-DI: 081006243MSN12T	
REF number	Description
45401	VACUMED Multi Sample Needle 20G*1
45402	VACUMED Multi Sample Needle 20G*1½
45403	VACUMED Multi Sample Needle 21G*1
45404	VACUMED Multi Sample Needle 21G*1½
45405	VACUMED Multi Sample Needle 22G*1
45406	VACUMED Multi Sample Needle 22G*1½

Generic device group	Safety Multi Sample Needle with Holder
EMDN code	A010199
Class	IIa
Rule	6
Sterility	Sterile, Single use
Intended Purpose	Safety Multi Sample Needle with Holder is intended to be used as a system in routine venepuncture/blood collection procedure. In the activated position, the safety shield protect against accidental needle stick injury during normal handling and disposal.

Type/Model: Safety Multi Sample Needle with Pre-Attached Holder	
Basic UDI-DI: 081006243SMS13N	
REF number	Description
45414	VACUMED Safety Multi Sample Needle with Pre-Attached Holder 21G*1½
45416	VACUMED Safety Multi Sample Needle with Pre-Attached Holder 22G*1½

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