



EU Declaration of Conformity TF-06 rev.01

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-06
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.

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**Medical Device
(Generic device group)**

Pen Needle

Conformity Assessment Procedure

Annex IX, Chapter I and III

Additional information

Regulatory Affairs Contact Point:



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16-Feb-2024

Manu Kalia
*Director, Quality Assurance
PRRC*

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Attachment 1

Generic device group	Pen Needle
EMDN code	A0101010202
Class	IIa
Rule	6
Sterility	Sterile
Intended Purpose	The Pen Needle consists of a needle hub, needle, small protective cap, large protective cap and other integral parts for use with a diabetic insulin pen filled with liquid insulin (such as the Novo Pen) for insulin injection.

Type/Model: Pen Needle	
Basic UDI-DI: 081006243penneedleKE	
REF number	Product name and Description
N42001	SOL-M Pen Needle 30G(0.3mm)*5/16(8mm)
N42002	SOL-M Pen Needle 31G(0.25mm)*15/64(6mm)
N42003	SOL-M Pen Needle 31G(0.25mm)*5/16(8mm)
N42004	SOL-M Pen Needle 31G(0.25mm)*3/16(5mm)
N42005	SOL-M Pen Needle 31G(0.25mm)*5/32(4mm)
N42006	SOL-M Pen Needle 29G(0.33mm)*1/2(12.5mm)
N42007	SOL-M Pen Needle 32G(0.23mm)*5/32(4mm)
N42008	SOL-M Pen Needle 33G(0.2mm)*5/32(4mm)
N42009	SOL-M Pen Needle 32G(0.23mm)*3/16(5mm)

-END of DOCUMENT-

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