

**EU Declaration of Conformity
TF-02 rev.05**

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-02

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

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**Medical Device
(Generic device group)**

Blunt Fill Needle

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: 9/11/2025 10:42:19 AM PDT

Edward Roles

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Director of RA, PRRC

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Attachment 1

Generic device group	Blunt Fill Needle
EMDN code	A010104
Class	Is
Rule	2
Sterility	Sterile, Single use
Intended Purpose	The Blunt Fill Needle is used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-slit septum covering injection sites.

Type/Model: Blunt Fill Needle Basic UDI-DI: 081006243BLT1XS	
REF number	Product name and description
110026	SOL-M Blunt Fill Needle, 16G*1 1/2"
110021	SOL-M Blunt Fill Needle, 18G*1"
110021EU	SOL-M Blunt Fill Needle, 18G*1"
110022	SOL-M Blunt Fill Needle, 18G*1 1/2"
110022EU	SOL-M Blunt Fill Needle, 18G*1 1/2"
110023	SOL-M Blunt Fill Needle, 18G*50mm
110023EU	SOL-M Blunt Fill Needle, 18G*50mm
110051	SOL-M Blunt Fill Needle, 19G*1"
110052	SOL-M Blunt Fill Needle, 19G*1 1/2"
110032	SOL-M Blunt Fill Needle, 20G*1 1/2"
110042	SOL-M Blunt Fill Needle, 22G*1 1/2"
110021I	SOL-M Blunt Fill Needle, 18G*1"
110022I	SOL-M Blunt Fill Needle, 18G*1 1/2"
110023I	SOL-M Blunt Fill Needle, 18G*2"
BN1815	Blunt Fill Needle, 18G*1 1/2"

Type/Model: Blunt Fill Needle with Filter Basic UDI-DI: 081006243BLT3XW	
REF number	Product name and description
110021F	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1"
110021FEU	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1"
110022F	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1 1/2"
110022FEU	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1 1/2"
110023F	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*50mm
110023FEU	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*50mm
110051F	SOL-M Blunt Fill Needle w/5 Micron Filter 19G*1"
110052F	SOL-M Blunt Fill Needle w/5 Micron Filter 19G*1 1/2"

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110021FI	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1"
110022FI	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*1 1/2"
110023FI	SOL-M Blunt Fill Needle w/5 Micron Filter, 18G*2"
BN1815F	Blunt Fill Needle With 5 Micron Filter, 18G*1 1/2"

Type/Model: Blunt Tip Aspirating Needle	
Basic UDI-DI: 081006243BLT2XU	
REF number	Product name and description
110101070029	SOL-M Blunt Tip Aspirating Needle, 16G*3 1/2"

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