EU DECLARATION OF CONFORMITY
No. 0003 Rev.00

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	EC REP Sol-Millennium Europe Sp. z o. o. Twarda 18 00-105 Warsaw Poland
European Authorized Representative's Single Registration Number (SRN)	PL-AR-000010397
Medical Device (Generic device group)	Blunt Fill Needle
Risk class	Class Is; rule 2
Conformity Assessment Procedure	Annex IX, Chapter I and III

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, 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 and harmonized standards listed below.

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

Sol-Millennium Medical, Inc.
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Notified Body	Conformity assessment was carried out by the manufacturer with the participation of the Notified Body: BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Identification Number: 2797 The devices have been marked with the CE mark and obtained the MDR Certificate of Conformity No. MDR 766495 R000 valid until 07/11/2027. (dd/mm/yyyy) CE 2797
Validity	This EU Declaration of Conformity has a validity until 07/11/2027 expiration of MDR Certificate. (dd/mm/yyyy)
Place	Suwanee, Georgia 30024, USA
On behalf of the Manufacturer	 Manu Kalia *Director, Quality Assurance* 09-Nov-2022 Date
Additional information	Regulatory Affairs Contact Point: EMEA_QRA@sol-m.com

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LIST OF STANDARDS

Standard	Title
EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7 :2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

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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.**

Reference number	**Description**
Type/Model: Blunt Fill Needle, Basic UDI-DI: 081006243BLT1XS	
110026	SOL-M Blunt Fill Needle 16G*1 1/2"
110021	SOL-M Blunt Fill Needle 18G*1"
110022	SOL-M Blunt Fill Needle 18G*1 1/2"
BN1815	SOL-M Blunt Fill Needle 18G*1 1/2"
110023	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"
Type/Model: Blunt Fill Needle with Filter, Basic UDI-DI: 081006243BLT3XW	
110021F	SOL-M Blunt Fill Needle w/Filter 18G*1"
110022F	SOL-M Blunt Fill Needle w/Filter 18G*1 1/2"
BN1815F	SOL-M Blunt Fill Needle w/Filter 18G*1 1/2"
110023F	SOL-M Blunt Fill Needle w/Filter 18G*50mm
110051F	SOL-M Blunt Fill Needle w/Filter 19G*1"
110052F	SOL-M Blunt Fill Needle w/Filter 19G*1 1/2"
Type/ Model: Blunt Tip Aspirating Needle, Basic UDI-DI: 081006243BLT2XU	
110101070029	SOL-M Blunt Tip Aspirating Needle 16G*3 1/2"

-END of DOCUMENT-

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