





EU DECLARATION OF CONFORMITY
No. 0008 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	 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)	Oral Dispensing Syringe Oral Dispensing Syringe (non-sterile) Catheter Tip Syringe
Risk class	Oral Dispensing Syringe – class Im+s; rule 5 Oral Dispensing Syringe (non-sterile) – class Im; rule 5 Catheter Tip Syringe – class Im+s; 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.

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<p>Notified Body</p>	<p>Conformity assessment was carried out by the manufacturer with the participation of the Notified Body:</p> <p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Identification Number: 2797</p> <p>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)</p> <p>CE₂₇₉₇</p>
<p>Validity</p>	<p>This EU Declaration of Conformity has a validity until 07/11/2027 expiration of MDR Certificate. (dd/mm/yyyy)</p>
<p>Place</p> <p>On behalf of the Manufacturer</p>	<p>Suwanee, Georgia 30024, USA</p> <p></p> <hr/> <p>Manu Kalia <i>Director, Quality Assurance</i></p> <p align="right">09-Nov-2022</p> <hr/> <p align="right">Date</p>
<p>Additional information</p>	<p>Regulatory Affairs Contact Point:</p> <p> EMEA_QRA@sol-m.com</p>

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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 10993-5:2009	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 skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
BS 3221-7: 1995	Specification for oral syringes delivering doses up to and including 5 ml

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Generic device group	Oral Dispensing Syringe
EMDN code	A020199
Class	Im+s
Rule	Rule 5
Sterility	Sterile, Single use
Intended purpose	The Oral Dispensing Syringe is intended for the delivery of liquid medication.

Reference number	Description
Type/ Model: Oral Dispensing Syringe (O-Ring type), Basic UDI-DI: 081006243ORL638	
210010C	SOL-M 1ml Oral Dispensing Syringe Clear w/Tip Cap
210030C	SOL-M 3ml Oral Dispensing Syringe Clear w/Tip Cap
210050C	SOL-M 5ml Oral Dispensing Syringe Clear w/Tip Cap
210100C	SOL-M 10ml Oral Dispensing Syringe Clear w/Tip Cap
210010A	SOL-M 1ml Oral Dispensing Syringe Amber w/Tip Cap
210030A	SOL-M 3ml Oral Dispensing Syringe Amber w/Tip Cap
210050A	SOL-M 5ml Oral Dispensing Syringe Amber w/Tip Cap
200100A	SOL-M 10ml Oral Dispensing Syringe Amber w/Tip Cap
210100A	SOL-M 10ml Oral Dispensing Syringe Amber with Tip Cap
210010P	SOL-M 1ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
210030P	SOL-M 3ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
210050P	SOL-M 5ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
210100P	SOL-M 10ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
210200P	SOL-M 20ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
Type/ Models: Oral Dispensing Syringe (Gasket type), Basic UDI-DI: 081006243ORL434	
21001GC	SOL-M 1ml Oral Dispensing Syringe Clear w/Tip Cap

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Reference number	Description
21003GC	SOL-M 3ml Oral Dispensing Syringe Clear w/Tip Cap
21005GC	SOL-M 5ml Oral Dispensing Syringe Clear w/Tip Cap
21010GC	SOL-M 10ml Oral Dispensing Syringe Clear w/Tip Cap
21020GC	SOL-M 20ml Oral Dispensing Syringe Clear w/Tip Cap
21005GA	SOL-M 5ml Oral Dispensing Syringe Amber w/Tip Cap
21003GA	SOL-M 3ml Oral Dispensing Syringe Amber w/Tip Cap
21010GA	SOL-M 10ml Oral Dispensing Syringe Amber w/Tip Cap
21001GA	SOL-M 1ml Oral Dispensing Syringe Amber w/Tip Cap
21020GA	SOL-M 20ml Oral Dispensing Syringe Amber w/Tip Cap

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Generic device group	Oral Dispensing Syringe (non-Sterile)
EMDN code	A020199
Class	Im
Rule	Rule 5
Sterility	Non-Sterile, Single use
Intended purpose	The Oral Dispensing Syringe is intended for the delivery of liquid medication

Reference number	Description
Type/ Models: Oral Dispensing Syringe (O-Ring), Basic UDI-DI: 081006243ORL22Y	
210200CBA	SOL-M 20ml Oral Dispensing Syringe Clear with Pre-attached Bottle Adapter (non-sterile)
B21005OC	SOL-M 5ml Oral Dispensing Syringe w/o Tip Cap (Bulk) (non-sterile)
Type/ Models: Oral Dispensing Syringe (Gasket type), Basic UDI-DI: 081006243ORL73A	
21001GCNSB	SOL-M 1ml Oral Dispensing Syringe Clear w/Tip Cap (bulk, non-sterile)
21003GCNSB	SOL-M 3ml Oral Dispensing Syringe Clear w/Tip Cap (bulk, non-sterile)
21005GCNSB	SOL-M 5ml Oral Dispensing Syringe Clear w/Tip Cap (bulk, non-sterile)
21010GCNSB	SOL-M 10ml Oral Dispensing Syringe Clear w/Tip Cap (bulk, non-sterile)
21001GANSB	SOL-M 1ml Oral Dispensing Syringe Amber w/Tip Cap (bulk, non-sterile)
21003GANSB	SOL-M 3ml Oral Dispensing Syringe Amber w/Tip Cap (bulk, non-sterile)
21005GANSB	SOL-M 5ml Oral Dispensing Syringe Amber w/Tip Cap (bulk, non-sterile)
21010GANSB	SOL-M 10ml Oral Dispensing Syringe Amber w/Tip Cap (bulk, non-sterile)

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Generic device group	Catheter Tip Syringe
EMDN code	A02010203
Class	Im+s
Rule	Rule 2
Sterility	Sterile, Single use
Intended use	The Catheter Tip Syringe is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.

Reference number	Description
Type/ Models: Catheter Tip Syringe, Basic UDI-DI: 081006243ORL11WQ	
180060CT	SOL-M 60ml Catheter Tip Syringe
180100CT	SOL-M 100ml Catheter Tip Syringe
180060CTBS	SOL-M 60ml Catheter Tip Syringe (bulk)
180100CTBS	SOL-M 100ml Catheter Tip Syringe (bulk)
IRS002	SOL-M 60ml Catheter Tip Syringe (with aspiration ring, luer adaptor)
IRS003	SOL-M 60ml Catheter Tip Syringe (with aspiration ring, luer adaptor, tip cap)

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