



EU Declaration of Conformity TF-09 rev.05

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-09
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)**

- Oral Dispensing Syringe
- Oral Dispensing Syringe (non-sterile)
- Catheter Tip Syringe

Conformity Assessment Procedure

Annex IX, Chapter I and III

Additional information

Regulatory Affairs Contact Point:



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Suwanee, Georgia 30024, USA

DocuSigned by:

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9/20/2023

Manu Kalia
Director, Quality Assurance
PRRC

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Attachment 1

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.

Type/Model: Oral Dispensing Syringe (O-Ring type)	
Basic UDI-DI: 081006243ORL638	
REF number	Description
21001OC	SOL-M 1ml Oral Dispensing Syringe Clear w/Tip Cap
21003OC	SOL-M 3ml Oral Dispensing Syringe Clear w/Tip Cap
21005OC	SOL-M 5ml Oral Dispensing Syringe Clear w/Tip Cap
21010OC	SOL-M 10ml Oral Dispensing Syringe Clear w/Tip Cap
21001OA	SOL-M 1ml Oral Dispensing Syringe Amber w/Tip Cap
21003OA	SOL-M 3ml Oral Dispensing Syringe Amber w/Tip Cap
21005OA	SOL-M 5ml Oral Dispensing Syringe Amber w/Tip Cap
20010OA	SOL-M 10ml Oral Dispensing Syringe Amber w/Tip Cap
21010OA	SOL-M 10ml Oral Dispensing Syringe Amber with Tip Cap
21001OP	SOL-M 1ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
21003OP	SOL-M 3ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
21005OP	SOL-M 5ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
21010OP	SOL-M 10ml Oral Dispensing Syringe Purple Plunger w/Tip Cap
21020OP	SOL-M 20ml Oral Dispensing Syringe Purple Plunger w/Tip Cap

Type/Model: Oral Dispensing Syringe (Gasket type)	
Basic UDI-DI: 081006243ORL434	
REF number	Description
21001GC	SOL-M 1ml Oral Dispensing Syringe Clear w/Tip Cap
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.

Type/Model: Oral Dispensing Syringe (O-Ring)	
Basic UDI-DI: 081006243ORL22Y	
REF number	Description
21020OCBA	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)
21001OCBA	SOL-M 2x1ml Oral Dispensing Syringe Clear with Bottle Adapter (non-sterile)

Type/Model: Oral Dispensing Syringe (Gasket type)	
Basic UDI-DI: 081006243ORL73A	
REF number	Description
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 Purpose	The Catheter Tip Syringe without a Needle is used to irrigate, withdraw fluids from, or instill fluids into, a body cavity or wound. This medical device is indicated and designed for the connection to non-Luer connections such as nasogastric tubes or for irrigation procedures, includes manual aspiration and dispensing of water. The medicinal products admixture shall be done according to the respective SmPCs (Summary of Product Characteristics) of the drugs.

Type/Model: Catheter Tip Syringe	
Basic UDI-DI: 081006243ORL11WQ	
REF number	Description
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 w/o Needle (with luer adapter, no tip cap)
IRS003	SOL-M 60ml Catheter Tip Syringe (with aspiration ring, luer adaptor, tip cap)

-END of DOCUMENT-

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