EU Declaration of Conformity
TF-09 rev.09

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-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.

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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: EMEA_QRA@solm.com

Chicago, Illinois, 60606, UNITED STATES

Signed by:
Edward Roles
Signer Name: Edward Roles
Signing Reason: I approve this document
Signing Time: 2/10/2026 | 6:27:39 AM PST
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Edward Roles
Director of RA, 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	**Product name and description**
21001OC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 1ml
21003OC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 3ml
21005OC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 5ml
21010OC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 10ml
21001OA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 1ml
21003OA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 3ml
21005OA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 5ml
20010OA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 10ml
21010OA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 10ml
21001OP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 1ml
21003OP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 3ml
21005OP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 5ml
21010OP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 10ml
21020OP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 20ml

Type/Model: Oral Dispensing Syringe (Gasket type) **Basic UDI-DI: 081006243ORL434**	
REF number	**Product name and description**
21001GC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 1ml
21003GC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 3ml
21005GC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 5ml
21010GC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 10ml
21020GC	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 20ml
21005GA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 5ml
21003GA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 3ml
21010GA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 10ml
21001GA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 1ml
21020GA	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 20ml
21001GP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 1ml
21003GP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 3ml
21005GP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 5ml
21010GP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 10ml
21020GP	SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap, 20ml

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21001AP	Sol-M Oral Dispensing Syringe Amber Plunger without Tip Cap, 1ml
21003AP	Sol-M Oral Dispensing Syringe Amber Plunger without Tip Cap, 3ml
21005AP	Sol-M Oral Dispensing Syringe Amber Plunger without Tip Cap, 5ml
21010AP	Sol-M Oral Dispensing Syringe Amber Plunger without Tip Cap, 10ml
21020AP	Sol-M Oral Dispensing Syringe Amber Plunger without Tip Cap, 20ml

Generic device group	Oral Dispensing Syringe (Non-Sterile)
EMDN code	A020199
Class	Im
Rule	Rule 5
Sterility	Non-Sterile. Single patient, multiuple 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	**Product name and description**
21020OCBA	SOL-M 20ml Oral Dispensing Syringe Clear with Pre-attached Bottle Adapter
B21005OC	SOL-M 5ml Oral Dispensing Syringe w/o Tip Cap (Bulk)
21001OCBA	SOL-M 2x1ml Oral Dispensing Syringe Clear with 1 Bottle Adapter
21005OAFP	Sol-M 5ml Oral Dispensing Syringe Amber (non-sterile, individual PE bag)
20010OAFP	Sol-M 10ml Oral Dispensing Syringe Amber (non-sterile, individual PE bag)
21005OCFP	Sol-M 5ml Oral Dispensing Syringe Clear (non-sterile, individual PE bag)
21010OCFP	Sol-M 10ml Oral Dispensing Syringe Clear (non-sterile, individual PE bag)
21020OCFP	Sol-M 20ml Oral Dispensing Syringe Clear (non-sterile, individual PE bag)
2110BAFP	Sol-M Bottle Adaptor for Oral Syringe (D-28) (non-sterile, individual PE bag)
21001OAFP	Sol-M 1ml Oral Dispensing Syringe Amber (non-sterile, individual PE bag)
21001OCFP	Sol-M 1ml Oral Dispensing Syringe Clear (non-sterile, individual PE bag)

Type/Model: Oral Dispensing Syringe (Gasket type) **Basic UDI-DI: 081006243ORL73A**	
REF number	**Product name and description**
21001GCNSB	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 1ml, (bulk)
21003GCNSB	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 3ml, (bulk)
21005GCNSB	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 5ml, (bulk)
21010GCNSB	SOL-M Oral Dispensing Syringe Clear with Tip Cap, 10ml, (bulk)
21001GANSB	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 1ml, (bulk)
21003GANSB	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 3ml, (bulk)
21005GANSB	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 5ml, (bulk)
21010GANSB	SOL-M Oral Dispensing Syringe Amber with Tip Cap, 10ml, (bulk)

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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	**Product name and description**
180060CT	SOL-M Catheter Tip Syringe without Needle, 60ml
180100CT	SOL-M Catheter Tip Syringe without Needle, 100ml
180060CTBS	SOL-M Catheter Tip Syringe, 60ml, (bulk)
180100CTBS	SOL-M Catheter Tip Syringe, 100ml, (bulk)
IRS002	SOL-M Catheter Tip Syringe with Luer Adapter, 60ml (no tip cap)
IRS003	SOL-M 60ml Catheter Tip Syringe (with aspiration ring, luer adaptor, tip cap)
IRS004	SOL-M 60ml Catheter Tip Syringe without Tip Cap

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