



**EU Declaration of Conformity
TF-14 rev.03**

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-14

Basic UDI-DI: See Attachment 1

Device Identification: See Attachment 1

Risk Class and Rule(s): See Attachment 1

Notified Body: Not Applicable

Notified Body Number: Not Applicable

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.

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**Medical Device
(Generic device group)**

Blood Collection Holder

Conformity Assessment Procedure

Annex IX, Chapter I and III

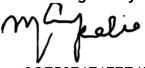
Additional information

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26-Jan-2024

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Director, Quality Assurance
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Attachment 1

Generic device group	Blood Collection Holder
EMDN code	A01018001
Class	I
Rule	1
Sterility	Non-sterile
Intended Purpose	The Blood Collection Tube Holder is intended to be used with blood collection needle, tube or bottle, and luer adapter as a system in routine venipuncture procedures to draw blood samples from a patient

Type/Model: Standard Blood Collection Holder	
Basic UDI-DI: 081006243BCA1UL	
REF number	Description
110201050001	SOL-M Blood Collection Tube Holder
BCA027	SOL-M Blood Collection Tube holder
110201050002	SOL-M Blood Culture Holder
Type/Model: Safety Blood Collection Holder	
Basic UDI-DI: 081006243BCD1UV	
REF number	Description
7001BCD	SOL-CARE Blood Collection Tube Holder Set with Vacuum Activation Tube
BCA019	SOL-CARE Safety Shield Blood Collection Tube Holder
BCA028	SOL-CARE Fast Release Blood Collection Tube Holder

-END of DOCUMENT-

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