

**EU Declaration of Conformity
TF-14 rev.04**

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-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.

311 S. Wacker, Suite 4100,
Chicago, IL 60606

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**Medical Device
(Generic device group)**

- Blood Collection Holder

Conformity Assessment Procedure

Annex IX, Chapter I and III

Additional information

Regulatory Affairs Contact Point:



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3-sep-2024

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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	Product name and 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	Product name and 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

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