EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 766495 R000

Manufacturer: SOL-Millennium Medical, Inc.

Address:
315 Shawnee North Drive, Suite 100
Suwanee
Georgia
30024
USA

Single Registration Number: US-MF-000010890

EU Authorised Representative: Sol-Millennium Europe Sp. z o.o.

Address:
Twarda 18,
00-105 Warsaw,
Poland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-08**

Current Issue Date: **2022-12-19**

Starting Validity Date: **2022-12-19**

Expiry Date: **2027-11-07**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Needles for Infusion and Sampling	Class IIa
Single-Use Syringes	Class IIa
Needles	Class Is
Syringes	Class Im
Syringes	Class Im, Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-11-08	3634810	Issued
Current	3832668	Supplemented – Addition of device categories "single-use needles" and "needles for infusion and sampling".

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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