

# 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.

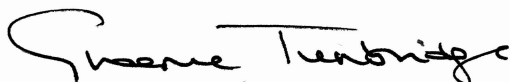
**Address:**

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: **2022-11-08**

Starting Validity Date: **2022-11-08**

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

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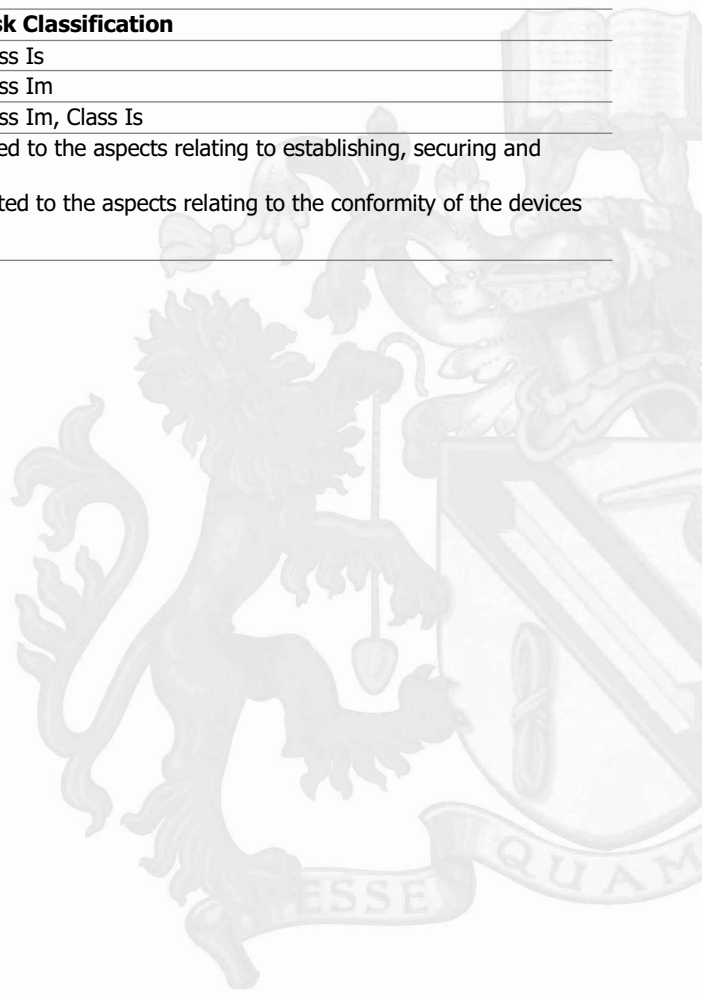
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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
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
Current	3634810	Issued



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