






**DECLARATION OF CONFORMITY**

Manufacturer	 <p>SOL-MILLENNIUM MEDICAL INC. 1735 NORTH BROWN ROAD, SUITE 120 LAWRENCEVILLE, GEORGIA 30043, USA</p>
European Authorized Representative	 <p>Obelis s.a. Bd Général Wahis 53, B-1030 Brussels, Belgium Tel: +3227325954 Fax: +3227326003 Email: mail@obelis.net Representative: Mr. Gideon ELKAYAM</p>
Medical Devices	SOL-M™ Blunt Fill Needle SOL-M™ Blunt Fill Needle W/ 5 Micron Filter
Classification Rule	Class IIa per rule 2 in accordance of the Council Directive MDD 93/42/EEC
Conformity Assessment Route	Annex V, VII
<p>We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.</p>	
Notified Body	<ul style="list-style-type: none"> <li>• BSI Group The Netherlands B.V.</li> <li>• BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP</li> </ul> <p>BSI operates two full scope Notified Bodies, which cover all NBOG codes for the Medical Device Directives (MDD).</p> <p>Sol-Millennium is migrating all products originally issues by BSI UK (0086) to BSI Group The Netherlands B.V. (2797). Either Identification number may be used through the completion of the migration.</p>
Identification Number	 or 
Validity	This Declaration of Conformity has a validity until 2022/08/21, expiration of EC Certificate.
Place of Declaration	Lawrenceville, GA
Authorized Signatory:	 <p>Pascualito Pasia Jr Director, Regulatory Affairs</p> <p style="text-align: right;"><u>11 FEBRUARY 2021</u> Date</p>



<b>SOL-M™ Blunt Fill Needle</b>		
<b>Label Code</b>	<b>Product description</b>	<b>SAP code</b>
110021	SOL-M Blunt Fill Needle 18G*1"	110101070027
110022	SOL-M Blunt Fill Needle 18G*1 1/2"	110101070001
110023	SOL-M Blunt Fill Needle 18G*50mm	110101070003
110026	SOL-M Blunt Fill Needle 16G*1 1/2"	110101070028

<b>SOL-M™ Blunt Fill Needle W/ 5 Micron Filter</b>		
<b>Label Code</b>	<b>Product description</b>	<b>SAP code</b>
110023F	SOL-M Blunt Fill Needle w/Filter 18G*50mm	110101070004
110022F	SOL-M Blunt Fill Needle w/Filter 18G*1 1/2"	110101070002
110021F	SOL-M Blunt Fill Needle w/Filter 18G*1"	110101070026

B. Braun Melsungen AG - Document No.: NA - Version: 2.0 - Document ID: DC-RA-IVA-000002 - Effective Date: 2021-02-24 -  
Title: Declaration of Conformity - DoC-002 - SOL-M Blunt Fill Needle