



**SOL-MILLENNIUM<sup>®</sup>**  
*Building a healthier tomorrow*

### DECLARATION OF CONFORMITY

Manufacturer:	Sol-Millennium Medical, Inc. 1735 North Brown Road Suite 120 Lawrenceville, GA 30043
Classification rule:	Class IIa per Rule 2 in accordance of the Council Directive MDD 93/42/EEC
Management Representative:	Lanis B. Henry Sr. Quality Engineer
European Authorized Representative:	Registered Address: Obelis s.a. Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: mail@obelis.net Representative: Mr. Gideon ELKAYAM
Medical Device(s):	SOL-M™ Blunt Fill Needle SOL-M™ Blunt Fill Needle with 5 Micron filter See the attached product details.

We hereby declare that the distributed CE marked product SOL-M™ Blunt Fill Needle, SOL-M™ Blunt Fill Needle with 5 Micron filter conform to the type(s) covered by Certificate of Registration, Quality System Management – ISO 13485:2003, Certificate Number FM 576929 issued on October 11, 2011 by BSI, 12950 Worldgate Drive, Suite 800, Herndon, VA 20170.


In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive that apply to them.

This declaration is based on Annex VII and Annex V according to Article 11 of the Council Directive 93/42/EEC.

This declaration is based on the application of the Quality System approved for the manufacturer and final inspection of the products concerned, in accordance with Annex VII of the EC Directive. The conformity of the production quality assurance set out in Annex VII, coupled with the procedure set out in Annex V, is described in the CE Marking of Conformity Certificate, reference number CE 584545 issued for the first time on August 22, 2012, reissued on December 20, 2015, and delivered by BSI Healthcare located at Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK.

This Declaration of Conformity covers the SOL-M™ Blunt Fill Needle, SOL-M™ Blunt Fill Needle with 5 Micron filter. This declaration is valid for all products concerned bearing the CE marking and manufactured at the above location entitled "Manufacturer".

**Issued:** Lawrenceville, GA on March 30, 2016

  
\_\_\_\_\_  
Mark Stoppenbach, President



**SOL-MILLENNIUM<sup>®</sup>**  
*Building a healthier tomorrow*

<b>SOL-M™ Blunt Fill Needle</b>			
<b>Product REF</b>	<b>Product Description</b>		<b>GMDN Code</b>
110020	--	20G x 1"	45316
110021	--	18G x 1"	45316
110022	--	18G x 1-1/2"	45316
110023	--	18G x 2"	45316
110025	--	22G x 1"	45316
110026	--	16G x 1-1/2"	45316
<b>SOL-M™ Blunt Fill Needle with 5 Micron filter</b>			
110021F	w/filter	18G x 1"	45316
110022F	w/filter	18G x 1-1/2"	45316
110023F	w/filter	18G x 2"	45316