



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 584545
Issued To: Sol-Millennium Medical, Inc.
1735 North Brown Road
Suite 120
Lawrenceville
Georgia
30043
USA

In respect of:

The manufacture of sterile safety syringes, standard syringes, safety needles, hypodermic needles and blunt fill needles.

Those aspects of manufacture related to metrology, securing and maintaining the sterility of oral syringes.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2012-08-22**

Date: **2017-08-23**

Expiry Date: **2022-08-21**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Hangzhou Longde Medical Products Co., Ltd. No. 510 Shunfeng Road Qianjiang Economic Development Zone 311106 Hangzhou Zhejiang China	Manufacture
Obelis s.a. Bd. Général Wahis 53 Brussels 1030 Belgium	EU Representative
Shanghai Kindly Enterprise Development Group Co. 658 Gaochao Road Shanghai, 201803 China	ETO Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Sol-Millennium Medical Products Co., Ltd No. 45, Fangyuan Street Industrial Park, Suzhou China	Final Inspection Manufacture
SOL-Millennium Medical, Inc 315 Shawnee North Drive Suite 100 Suwanee Georgia 30024 USA	Distribution
Zhejiang Kindly Medical Devices Co., Ltd. No.758, 5th Binhai Road, Binhai Ind. Park, Longwan District, Wenzhou, Zhejiang Province 325025 China	ETO Sterilization Manufacture

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
22 August 2012	7804227	First issue.
15 January 2013	7900640	Extension of scope to include safety syringes, standard syringes and hypodermic needles. Addition of new subcontractor Shanghai Kindly Enterprise Development Group Co.
03 April 2013	7962349	Scope clarification to include safety needles.
25 February 2015	8139083	Extension to scope to include Class 1 sterile/measuring oral syringe. Addition of significant subcontractor Hangzhou Longde Medical Products Co., Ltd.
24 July 2015	8351679	Addition of significant subcontractor Sol-Millennium Medical Products Co., Ltd, Suzhou, China, for Final Inspection and Manufacture.
20 December 2015	8428801	Change to legal manufacturer address.
05 October 2016	8621736	Change in address for subcontractor, Zhejiang Kindly Medical Devices Co. Ltd.
Current	8792384	Certificate Renewal. Addition of significant subcontractor Sol Mil, Suwanee, GA for distribution.

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