

# EC Certificate - Production Quality Assurance

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

**No.** CE 02076  
**Issued To:** Puritan Medical Products Co LLC,  
31 School Street  
Guilford  
Maine  
04443-0149  
USA

In respect of:

**Those aspects of Annex V related to securing and maintaining sterility in the manufacture of: single use tongue depressors; cervical brushes; absorbent tipped applicators; and absorbent tipped specimen collection devices.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-09-16**

Date: **2019-11-27**

Expiry Date: **2023-09-15**

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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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## Supplementary Information to CE 02076

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NBOG Code(s)	Device Description	Intended Purpose
<b>Class Is</b>		
MDS 7006	Sterile Tongue Depressors Sterile Absorbent Tipped Applicators Sterile Cervical Brushes Sterile Absorbent Tipped Specimen Collection Devices	NA for Class Is devices

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Europe B.V. Prinsessegracht 20 The Hague 2514 AP The Netherlands	<b>EU Representative</b>
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	<b>ETO Sterilization Gamma Sterilization</b>
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	<b>ETO Sterilization</b>

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Date	Reference Number	Action
16 September 1998		First Issue.
08 November 1999		Addition of Steris Corporation, Massachusetts as subcontractor for ETO Sterilisation and change in name of Isomedix Services, Illinois (subcontractor for Gamma Sterilisation) to Steris Corporation.
27 August 2002		Change of scope of sterilisation subcontractor - addition of Gamma Sterilisation to Steris Corporation, Massachusetts.
24 January 2003		Company name change.
29 April 2004		Certificate renewal.
29 March 2006		Company name change. Removal of 'PO Box 149' from Company address. Change of subcontractor name from 'Cosmed Medical Sterilisation, Inc' to 'Steris Isomedix Services, Inc'. Update of certificate to new format.
01 September 2006		Company name changed from Hardwood Product Company LP d.b.a Puritan Medical Products Company LLC to Puritan Medical Products Company LLC.

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Date	Reference Number	Action
12 September 2008	7071161	Certificate renewal.
29 May 2012	7829296	Company name change from 'Puritan Medical Products Company LLC' to 'Puritan Medical Products Co LLC, d.b.a. Puritan Diagnostics LLC'. Removal of 'Steris Corporation, Coventry' as significant sub-contractor. Scope change - removal of 'cervical scrapers'.
26 September 2013	8032034	Certificate Renewal; Addition of EU Rep as a significant Sub-contractor. Scope change – Addition of 'absorbent'.
14 August 2018	8997514	Certificate renewal. Removal of company name "Puritan Diagnostics LLC" from certificate address. Emergo Europe address change. Removal of Steris Isomedix Services, Inc. Update to sterilization subcontractor name to "Isomedix Operations, Inc."



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Date	Reference Number	Action
28 February 2019	7781193	Traceable to NB 0086.
Current	3046276	Addition of subcontractor Sterigenics for the activity EO sterilisation. Addition of absorbent tipped specimen collection devices to the scope of certification. Inclusion of supplementary page to include device information.