By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 02076**

Issued To: **Puritan Medical Products Co LLC,**
d.b.a. Puritan Diagnostics 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, cytology devices and absorbent tipped applicators

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: **1998-09-16** Date: **2018-08-14** Expiry Date: **2023-09-15**

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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**
Emergo Europe B.V. Prinsessegracht 20 The Hague 2514 AP The Netherlands	**EU Representative**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**ETO Sterilization** **Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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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'
Current	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.".