

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hardwood Products Company LP
Also doing business as Puritan Medical
Products Company LLC
Also doing business as Puritan
Diagnostics LLC
31 School Street
Guilford
Maine
04443-0149
USA

Facility ID Number: F003220

Holds Certificate No:

MDSAP 703526

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The manufacture and distribution of disposable sterile and non-sterile tipped applicators, and sterile and non-sterile measuring medical devices, tongue depressors, cytology devices, and microbiological specimen collection and transport kits.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-11-30

Effective Date: 2023-02-23

Expiry Date: 2024-11-29



BSI Group America Inc. is an MDSAP recognised auditing organization

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Location	Registered Activities
Hardwood Products Company LP Also doing business as Puritan Medical Products Company LLC Also doing business as Puritan Diagnostics LLC 31 School Street Guilford Maine 04443-0149 USA Facility ID Number: F003220	Manufacture, warehouse, labelling and package.
Puritan Medical Products Company LLC 129 N. Main Street Pittsfield Maine 04967 USA Facility ID Number: F003220	Warehousing, Raw material storage, Manufacturing of Sterile absorbent tipped applicators (foam).
Puritan Medical Products Company LLC 3150 Barry Drive Portland Tennessee 37148 USA Facility ID Number: F005869	Warehousing, raw material storage. Manufacturing of sterile and non-sterile tipped applicators (foam).
Puritan Medical Products Company LLC 206 SAS Drive Pittsfield Maine 04967 USA Facility ID Number: F003220	Storage for production materials received from external and internal vendors. Manufacturing of Swabs using an electrostatic flocking process.

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.