By Royal Charter

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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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 Global Regulatory & Quality

Original Registration Date: 2021-11-30 Effective Date: 2024-11-30 Expiry Date: 2027-11-29

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 703526**

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 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.

Original Registration Date: 2021-11-30 Effective Date: 2024-11-30 Expiry Date: 2027-11-29

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

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.