

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hardwood Products Company LP
d.b.a. Puritan Medical Products
Company LLC
d.b.a. Puritan Diagnostics LLC
31 School Street
Guilford
Maine
04443-0149
USA

Holds Certificate No:

FM 703606

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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.

Previous certificate expired on 2019-02-28 (ISO 13485:2003 expiration)
Transition audit ended 2019-03-28

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-03-19

Latest Revision Date: 2019-04-02

Effective Date: 2019-04-02

Expiry Date: 2020-11-19



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