

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Remington Medical, Inc.
6830 Meadowridge Court
Alpharetta
Georgia
30005
USA

Facility ID Number: F003302

Holds Certificate No: **MDSAP 705124**

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 1 (excluding Part 1.6) - Full 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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-03-09

Effective Date: 2022-11-16

Expiry Date: 2025-11-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 705124**

Registered Scope:

The design, manufacture and distribution of the following sterile and non-sterile devices: Decanters, Drainage Bags, Soft Tissue Biopsy Needles, Introducer Needles-GWI, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Cables for Cardiac Procedures, Adapters and Doppler Cardiovascular Blood Flowmeter. The contract manufacture of Ocular Devices. Contract kit manufacture.



Original Registration Date: 2020-03-09

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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](#). 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 705124**

Location	Registered Activities
Remington Medical, Inc. 6830 Meadowridge Court Alpharetta Georgia 30005 USA Facility ID Number: F003302	The design, manufacture and distribution of the following sterile and non-sterile devices: Decanters, Drainage Bags, Soft Tissue Biopsy Needles, Introducer Needles-GWI, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Cables for Cardiac Procedures, Adapters and Doppler Cardiovascular Blood Flowmeter. The contract manufacture of Ocular Devices. Contract kit manufacture.
Remington Medical, Inc. 6245 Shiloh Road, Suite #C Alpharetta Georgia USA Facility ID Number: F003302	The design, manufacture and distribution of the following sterile and non-sterile devices: Decanters, Drainage Bags, Soft Tissue Biopsy Needles, Introducer Needles-GWI, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Cables for Cardiac Procedures. The design, manufacture sale and distribution of adapters, contract kit manufacture/packaging and biopsy instruments.



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