

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. 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

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-03-09

Effective Date: 2025-11-16

Expiry Date: 2028-11-15



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, Vascular Introducer Needles, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Extension Cables for Cardiac Procedures, Reusable Adapters, and Doppler Cardiovascular Blood Flowmeter with Sterile and Clinical Probes.

Contract Manufacture of Surgical Kits for Spinal Surgery, Force Modulating Tissue Bridge for Wounds, Flexible Threaded Device for Feeding Tubes, Ocelot Disposable Unit for Tendon Procedures, and VGC (Video Guided Catheter) for use with an Endoscope.



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](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.

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, Vascular Introducer Needles, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Cables for Cardiac Procedures, Reusable Adapters and Doppler Cardiovascular Blood Flowmeter with Sterile and Clinical Probes. 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, Vascular Introducer Needles, Bone Marrow Needles, General Surgical Trays, Breast Localization Needles, Disposable Cables for Cardiac Procedures. The design, manufacture, sale and distribution of reusable adapters. Contract kit manufacture/packaging.



Original Registration Date: 2020-03-09 Effective Date: 2025-11-16 Expiry Date: 2028-11-15

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