

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Remington Medical, S.A.
Zona Franca Industrial De Las Americas
Km 22 Autopista Las Americas
Santo Domingo Este
15001
Dominican Republic

Facility ID Number: F003317

Holds Certificate No:

MDSAP 705207

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

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

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

Manufacture of pacing cables and adapters; aspiration and injection needles; epidural needles; vascular introducer needles; biliary/urinary drainage bags; and doppler sterile and clinical probes. Contract manufacture of ocular cables and ocular gland evaluator devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-04-30

Effective Date: 2025-04-17

Expiry Date: 2026-03-26



BSI Group America Inc. is an MDSAP recognised auditing organization

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