

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Busse Hospital Disposables
75 Arkay Drive
Hauppauge
New York
11788
USA

Facility ID Number: F002587

Holds Certificate No:

MDSAP 699746

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and 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

The design, manufacture and distribution of single use: bulb syringe, sterile and non-sterile suction instruments, sterile cervical dilator, sterile aspiration tubing and connectors, Sterile and non-sterile LOR syringe, sterile needles, sterile surgical support procedure packs, and sterile towels/drapes.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-12-21

Effective Date: 2021-12-21

Expiry Date: 2024-08-19



BSI Group America Inc. is an MDSAP authorized auditing organization

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