

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

Holds Certificate Number:

FM 701461

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

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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2003-10-28

Latest Revision Date: 2024-06-07

Effective Date: 2024-08-20

Expiry Date: 2027-08-19

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