

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Busse Hospital Disposables
75 Arkay Drive
Hauppauge
New York
11788
USA

Holds Certificate No:

FM 77400

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 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:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 10/28/2003

Effective Date: 09/04/2015

Expiry Date: 09/03/2018



CMDCAS
Recognized
Registrar



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