

CERTIFICATE OF REGISTRATION

Quality Management System

This is to certify that

Ethox International
251 Seneca Street
Buffalo
New York
14204
USA



Hold Certificate No: **MD 96988**

and operate a Quality Management System which complies with the requirements of **ISO 13485:2003** for the following scope:

The design, development, manufacture and distribution of sterile and non-sterile instrument holders and accessories, blood pressure cuffs and accessories, bio-process containers, wound irrigation devices and pressure infusion devices. This includes the following device families: Surgi-cuf Neonatal Blood Pressure Cuffs, Surgi-cuf Blood Pressure Cuffs, Gastric Lavage Kits, Lavage Tubes with Connectors - PVC, and Combiport. Provision for subcontract design, manufacture and packaging for medical devices and sterilization and laboratory services in accordance with ISO 11135-1:2007

For and on behalf of BSI:

A handwritten signature in black ink, appearing to read 'David W. Ford', written over a horizontal line.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 23 May 2005

Date: 13 May 2011

Expiration Date: 23 Mar 2013



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Group Headquarters: 389 Chiswick High Road, London W4 4AL, UK.



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Location	Registered Activities
Ethox International 251 Seneca Street Buffalo New York 14204 USA	The design, development, manufacture and distribution of sterile and non-sterile instrument holders and accessories, blood pressure cuffs and accessories, bio-process containers, wound irrigation devices and pressure infusion devices. This includes the following device families: Surgi-cuf Neonatal Blood Pressure Cuffs, Surgi-cuf Blood Pressure Cuffs, Gastric Lavage Kits, Lavage Tubes with Connectors - PVC, and Combiport. Provision for subcontract design, manufacture and packaging for medical devices and sterilization and laboratory services in accordance with ISO 11135-1:2007
Ethox International MMC Sterilization Services Group 2205 East 33rd Street Erie Pennsylvania 16510 USA	The design, development, manufacture and distribution of sterile and non-sterile instrument holders and accessories, blood pressure cuffs and accessories, bio-process containers, wound irrigation devices and pressure infusion devices. This includes the following device families: Surgi-cuf Neonatal Blood Pressure Cuffs, Surgi-cuf Blood Pressure Cuffs, Gastric Lavage Kits, Lavage Tubes with Connectors - PVC, and Combiport. Provision for subcontract design, manufacture and packaging for medical devices and sterilization and laboratory services in accordance with ISO 11135-1:2007
Ethox International STS Life Sciences Division 7500 Henrietta Road Rush New York 14543 USA	Provision of laboratory technical services for medical and EO sterilization of medical devices in accordance with ISO 11135-1:2007

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