

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 01574****Issued To:**

**Northgate Technologies Inc.
(Nortech)
1591 Scottsdale Court
Elgin
Illinois
60123
USA**

In respect of:

The design and manufacture of medical devices and accessories for sterile and non-sterile insufflation, hysteroflation and intracorporeal lithotripsy. Those aspects of Annex II concerned with securing and maintaining sterile conditions of irrigation pumps for urology and arthroscopy.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-03-27**

Date: **2019-06-14**

Expiry Date: **2023-01-03**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 01574

Issued To:

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NBOG Codes	Device Name	Intended purpose per IFU
Class Is		
MD 0102	Flo-Assist II	To facilitate gravity flow of irrigation fluid and additional bolus flow on demand for the purpose of endoscopic visualization during Urologic and Arthroscopic procedures.
Class IIa		
MD 1104 MD 1101 MDS 7010	Nebulae Insufflator	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 1104 MD 1101 MDS 7010	S&N 500 Insufflator	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 1104 MD 1101 MDS 7010	GS2000 Insufflator	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 1104 MD 1101	In-Line Gas Warmers	Minimally Invasive Surgical Procedures CO2 Insufflation

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Insufflation Tubing Sets	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	High Flow Insufflation Tubing Sets	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	Shuttle Valve System	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	Hose / Yoke	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	Adapter for Hoses	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	CPC to IEC Adapter	Minimally Invasive Surgical Procedures CO2 Insufflation
MD 0102	CPC to Luer Adapter	Minimally Invasive Surgical Procedures CO2 Insufflation

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1104 MD 1404	Probes	Biliary and Urinary Stone Lithotripsy
MD 1104 MD 1404	1.9FR 375cm Probe	Biliary Stone Lithotripsy
Class IIb		
GMDN 35711	AutoLith Touch (9-202-00)	Biliary Stone Lithotripsy
GMDN 35711	AutoLith Uro-Touch	Urinary Stone Lithotripsy
GMDN 35711	AutoLith Touch (72-00275-0)	Biliary Stone Lithotripsy
GMDN 35711	Extender Cables (9-002-00, 9-004-00)	Biliary and Urinary Stone Lithotripsy
GMDN 35711	Extender Cable (72-00325-0)	Biliary Stone Lithotripsy

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization

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Date	Reference Number	Action
27 March 1997		Original issue.
7 January 1998		Addition of subcontractors. Change of scope.
27 January 1999		Change of scope – addition of sterile and non-sterile IEHL probes.
8 October 1999		Change of scope – addition of Intracorporeal Electro-Hydraulic Lithriptors.
9 May 2000		Change of scope wording to allow the addition of accessories.
11 February 2003		Addition of subcontractors. Reconfirmation of certificate.
11 May 2005		Change of sub-contractor and modification of scope to enhance regulatory compliance.
10 July 2006		Rename of sub-contractor 'SGS Northview Laboratories'.
26 October 2007		Certificate renewal.
11 November 2009	7457700	Certificate re-issue due to change of company address.

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Date	Reference Number	Action
17 December 2012	7915328	Certificate renewal. Addition of 'ABS-Bolton, France' as EU Representative. Deletion of, 'Medtronic Biomediscus Inc' as subcontractor. Change the name and address of subcontractor, SGS Northview Labs to 'SGS Life Science Services, 616 Heathrow Drive, Lincolnshire, Illinois, 60069, USA'. Three corrections to address of two subcontractors, Sterigenics U. S., Inc., zip code 60527 and not zip code 60521. Also 'Sterigenics U.S., Inc.', should be '10811 Withers Cove Park Drive' and not '10821 Charlotte North Carolina' with '28278' zip code and not zip code '28273'.
08 August 2017	8712214	Change of EU Rep from ABS Bolton to Emergo Europe and removal of subcontractor SGS and Sterigenics, 1500 West Thorndale, Itasca, Illinois, 601043, US.
19 January 2018	8814400	Certificate Renewal.
5 March 2019	7781672	Traceable to NB 0086.
Current	9750717	Added ETO Sterilization subcontractor Isomedix Operations, Inc. and device information table

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