

EC Certificate - Full Quality Assurance System

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

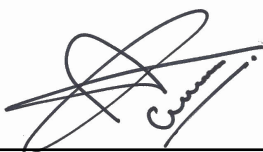
No. CE 01574
Issued To: **Northgate Technologies Inc.**
(Nortech)
1591 Scottsdale Court
Elgin
Illinois
60123
USA

In respect of:

The design and manufacture of medical devices and accessories for sterile and non-sterile insufflation, hysteroflation, intracorporeal lithotripsy, fluid management 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):



Albert Roossien, Regulatory Lead

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

Date: **2019-03-05**

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

...making excellence a habit.™

Page 1 of 1

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.

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 01574**
Date: **2019-03-05**
Issued To: **Northgate Technologies Inc.
(Nortech)
1591 Scottsdale Court
Elgin
Illinois
60123
USA**

Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Sterigenics US, LLC 7775 South Quincy Street Willowbrook Illinois 60527 USA	ETO Sterilization
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	Gamma Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 01574**
Date: **2019-03-05**
Issued To: **Northgate Technologies Inc.
(Nortech)
1591 Scottsdale Court
Elgin
Illinois
60123
USA**

Subcontractor:

Service(s) supplied

Sterigenics US, LLC
10811 Withers Cove Park Drive
Charlotte
North Carolina
28278
USA

Gamma Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01574**
 Date: **2019-03-05**
 Issued To: **Northgate Technologies Inc.
 (Nortech)
 1591 Scottsdale Court
 Elgin
 Illinois
 60123
 USA**

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.

...making excellence a habit.™

Page 1 of 2

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.

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.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01574**
 Date: **2019-03-05**
 Issued To: **Northgate Technologies Inc.
 (Nortech)
 1591 Scottsdale Court
 Elgin
 Illinois
 60123
 USA**

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.
Current	7781672	Traceable to NB 0086.