

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 81758****Issued To:**

**Northern Digital, Inc.
103 Randall Drive
Waterloo
Ontario
N2V 1C5
Canada**

In respect of:

Those aspects relating to securing and maintaining sterility in the manufacture of passive reflective spheres for use with spatial measurement systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2004-09-06**

Date: **2019-09-04**

Expiry Date: **2024-05-26**

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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 81758

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NBOG code(s)	Device Description	Intended purpose per IFU
Class Is		
MDS 7006	Passive reflective spheres for use with spatial measurement systems	NA for class Is devices

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List of Significant Subcontractors

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

Certificate No: **CE 81758**
 Date: **2019-09-04**
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103 Randall Drive
Waterloo
Ontario
N2V 1C5
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Subcontractor:

Service(s) supplied

Cosmed Group Inc.
 2205 East 33rd Street
 Erie
 Pennsylvania
 16510
 USA

ETO Sterilization

IIMAK Mexicana, S. de R.L. de C.V.
 Ave. Mike Allen 1220, Edificio 5
 Parque Industrial Reynosa
 Reynosa
 Tamaulipas
 C.P. 88780
 Mexico

**Assembly
 Packaging**

Medipack AG
 Mühllentalstraße 184-188
 Schaffhausen
 8200
 Switzerland

Packaging

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Subcontractor:	Service(s) supplied
NDI Europe GmbH Güttinger Strasse 37 D-78315 Radolfzell Germany	Assembly EU Representative
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	ETO Sterilization
Steritec, Inc 1705 Enterprise St, Athens Texas 75751 USA	ETO Sterilization

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Certificate History

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Date	Reference Number	Action
06 September 2004		First issue.
11 September 2009	7296868	Certificate renewal.
10 August 2010	7556594	Addition of significant subcontractors IIMAK Mexicana, Ethox International and NDI Europe GmbH.
15 November 2010	7605603	Addition of significant subcontractors Medipack AG and Sterigenics Germany.
17 August 2012	7868422	Removal of significant subcontractors Surgical Technologies Inc and STERIS Isomedix Services, Minnesota 55433, USA. Addition of Assembly to services supplied by significant subcontractor IIMAK Mexicana, S. de R.L. de C.V. EU representative NDI Europe GmbH address change from Fritz-Reichle-Ring 2, D-78315 Radolfzell, Germany to Güttinger Strasse 37, D-78315 Radolfzell, Germany.
05 September 2014	8214182	Addition of Assembly to services supplied by significant subcontractor NDI Europe GmbH. Change of name of significant subcontractor Ethox International, Inc. to MMC Sterilization Services Group, Inc. Certificate renewal.

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Date	Reference Number	Action
14 November 2014	8243632	Change of street address for significant subcontractor Sterigenics Germany GmbH from Rheingaustrasse 190-196 to Kasteler Straße 45.
12 November 2015	8418914	Change of name of significant subcontractor MMC Sterilization Services Group, Inc. to iuvo BioScience - Erie, LLC.
07 July 2018	8942581	Change of street address for significant subcontractor IIMAK Mexicana from Brecha E99 Norte to Ave. Mike Allen 1220. Change of name of significant subcontractor iuvo Bioscience - Erie, LLC to Cosmed Group Inc. Addition of significant subcontractor Steritec Inc. Clarification to the method of sterilization services supplied: Ethylene Oxide.
24 January 2019	7781233	Traceable to NB 0086.
Current	3057302	Certificate Renewal. Addition of supplementary page device table.

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