Tel: +1 (519) 884-5142
Fax: +1 (519) 884-5184
Toll Free: +1 (877) 634-6340
Global: +(800) 634-634-00

EC DECLARATION OF CONFORMITY

Manufacturer:	**NORTHERN DIGITAL INC.** 103 Randall Drive Waterloo, ON N2V 1C5 Canada
EU Representative:	**NDI Europe GmbH** Güttinger Strasse 37 D-78315 Radolfzell Germany
Identification of Medical Device:	**NDI Passive Spheres™** P/N: 8801071, 8801074, 8801075, 8801085
Date of Validity:	**25 June 2013**
Council Directive:	93/42/EEC, 2007/47/EC
Classification according to Annex IX:	Class I (Sterile)
Classification Route:	Annex VII and Annex V
Notified Body according to Annex XI:	BSI Healthcare Kitemark Court Davy Avenue Milton Keynes MK5 8PP
Notified Body No.:	0086
Harmonised Standards Applied:	See attachment

We, NDI, declare under our sole responsibility that:

- **the above-mentioned device is a medical device according to Council Directive 93/42/EEC Article 1 and meets the applicable provisions of this Directive and its amendments.**
- **the medical device complies with the Essential Requirements stated in Annex I of the Council Directive 93/42/EEC.**
- **the procedures referred to in Council Directive 93/42/EEC, Annex VII (EC Declaration of Conformity) and Annex V (Production quality assurance) have been followed.**

Dated at Waterloo, Ontario, Canada this 24 **day of** July **,** 2014 **.**

NORTHERN DIGITAL INC.
per:

David Rath
President, NDI

Digitally signed by Cucerenco Olesea
Date: 2020.05.04 13:17:11 EEST
Reason: MoldSign Signature
Location: Moldova

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Attachment to EC DECLARATION OF CONFORMITY
NDI Passive Spheres™

Harmonised Standards Applied:

Reference	Title of the harmonised standard
EN 980:2008	Symbols for use in the labeling of medical devices
EN 556-1:2001 **EN 556-1:2001/AC:2006**	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-1:2009 Technical Corrigendum 1
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-7:2008/AC:2009	EN ISO 10993-7:2008 Technical Corrigendum 1
EN ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2009	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-1:2006/AC:2009	EN ISO 11737-1:2006 Technical Corrigendum 1
EN ISO 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices