



As of \_\_\_\_\_ October \_\_\_\_\_

19

## EC DECLARATION OF CONFORMITY

We, Northgate Technologies, Incorporated  
1591 Scottsdale Court  
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INT + 847-608-8900  
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declare under our sole responsibility that our 50 LPM Insufflator, 72-00258-0 manufactured as "50L Insufflator for ConMed, Ref. GS2000 (Classification IIa, Rule 9 Annex IX), which this declaration relates, are in conformity with the following standard(s) or other normative document(s):

1. ISO 13485:2016, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.
2. Quality Management System, which demonstrates compliance with Annex II of the Medical Device Directive (93/42/EEC) (As amended by 2007/47/EC-M5).
3. RoHS – Restriction of Hazardous Substances of the Directive 2011/65/EU

Notified Body (NB 2797):  
Certificate number: CE 01574  
BSi  
Say Building, John M. Keynesplein 9,  
1066 EP Amsterdam,  
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The technical documentation maintained by:

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10/7/19

David McDonough, VP/General Manager  
Northgate Technologies, Inc.