DECLARATION OF CONFORMITY
FOR VERIGENE® ENTERIC PATHOGENS (EP) NUCLEIC ACID TEST
ON THE VERIGENE SYSTEM

Verigene® EP Test Kits
Test Kit (catalog number 20-005-023)
Amplification Kit (catalog number 20-012-023)

We declare that the Verigene® Enteric Pathogens (EP) Nucleic Acid Test Kits (catalog numbers 20-005-023 and 20-012-023), manufactured by Nanosphere Inc., conform to the requirements of the European Directive 98/79/EC for in vitro diagnostic medical devices when used with the Verigene Processor SP (catalog number: 10-0000-07) and Verigene Reader (catalog number: 10-0000-02).

The harmonized Standards to which conformity is declared are as follows:

- BS EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- EN 980:2008 Graphical symbols for use in the labeling of medical devices
- EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
- EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use

Nanosphere’s Authorized Representative located within the EU Community is Qarad b.v.b.a.

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Technical documentation demonstrating compliance is kept by the Manufacturer in the United States and can be made available by the EU Authorized Representative.

Sudhakar Marla
Vice President, Product Development

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