EC Declaration of Conformity

Manufacturer/Supplier Information:
BioFire Diagnostics, LLC
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We, BioFire Diagnostics, LLC, declare under our sole responsibility, that the product

FilmArray® Blood Culture Identification (BCID) Panel
(RFIT-ASY-0126, RFIT-ASY-0127)

meets the provisions of the European Directive 98/79/EC for In vitro Diagnostic Medical Devices. The device is classified as a General In Vitro Diagnostic (IVD) Device.


The following relevant standards have been met:

  Medical devices – Quality Management System – Requirements for regulatory purposes
- EN ISO 14971:2012
  Medical devices – Application of risk management to medical devices
- EN 13641:2002
  Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- EN 62366:2008
  Medical devices – Application of usability engineering to medical devices
- EN 13612:2002
  Performance evaluation of in vitro diagnostic medical devices
- EN ISO 23640:2015
  In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
- EN ISO 15223-1:2015
  Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- EN ISO 18113-1:2011
  In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definition 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

Technical documentation demonstrating compliance as described in Annex III of the European Directive 98/79/EC is kept by the manufacturer and can be made available by the authorized representative in Europe - QARAD bvba, Cipalstraat 3, B-2440 Geel, Belgium.

The notified body for this product is BSI (Notified body #0086; Kitemark Court, Davy Avenue, Knowthill, Milton Keynes, MK5 8PP, United Kingdom), Keynes, MK5 8PP, United Kingdom.

Salt Lake City, UT, USA
(Place of issue)
17-31-2018 (Date of issue)

Randy Rasmussen
Chief Executive Officer