



Meridian

Bioscience, Inc.

EC DECLARATION OF CONFORMITY

ImmunoCard STAT![®] HpSA[®]

This is to certify that the product ImmunoCard STAT![®] HpSA[®] (Catalog # 750720) is manufactured by Meridian Bioscience, Inc. for worldwide distribution. This product:

1. Complies with all Essential Requirements (Annex I) of the IVDD (Directive 98/79/EC).
2. This compliance has been properly documented using a checklist created from Annex I of the IVDD, linked to all supporting Technical Documentation. This documentation includes both product specific and process (Quality Systems) specific documents.
3. Meridian Bioscience has a Quality System in place, which is equivalent to the ISO-13485:2003 requirements. Documentation of this is included in the Technical Documentation..
4. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.



Susan Rolih

Vice President, Regulatory Affairs & Quality Assurance

6.29.04

Date