ALPHA SCIENTIFIC CORPORATION
HEADQUARTERS: MALVERN, PA, USA
P.O. Box 725 • Southeastern, PA 19399-0725 • USA
Phone: 610-647-7000 • Fax: 610-647-7496

# Declaration of Conformity

## Covering General IVD's .

I hereby declare that the Products listed on this schedule meet the relevant Essential Requirements of Annex I of the In Vitro Diagnostics Directive 98/79/EC.

We have compiled a Technical File in accordance with clause 3 of Annex III and confirm that our manufacturing processes follow the principles of quality assurance, as set out in clause 4 of annex III.

We have registered our Devices with the UK Competent Authority through our Authorized Representative, Medical Device & QA Services, 76, Stockport Road, Timperley, Cheshire. WA15 7SN. UK

## Product Schedule

**DIFF-SAFE – Blood Dispenser – Accessory to a Specimen Receptacle**

**SEG-SAFE – Blood Bank Segment processor – Accessory to a Specimen Receptacle.**

I further declare that we are implementing documented procedures covering the following;

1• Notification to the Competent Authority, of additions or changes to this Product Schedule, through our Authorized Representative.
2• Effective handling of Customer Complaints.
3• A Post Market Feedback system, to proactively gather information about our products, in the Post Sales Phase.
4• Identification of, and reporting to appropriate Competent Authorities, adverse and Near Incidents.
5• Implementation of Product Recall and issuance of Advisory Notices.

Signed: Marshall S. Levine Date: 4/5/04

Chairman