

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

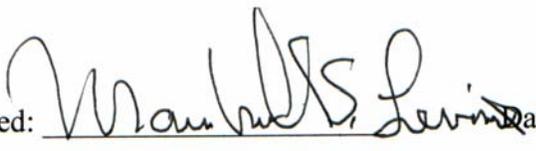
Product Schedule

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:  Date: 4/5/04

Chairman