TREK DIAGNOSTIC SYSTEMS

EC DECLARATION OF CONFORMITY

MANUFACTURER:

TREK Diagnostic Systems
982 Keynote Circle, Suite 6
Cleveland, Ohio 44131
USA

AUTHORIZED REPRESENTATIVE:

TREK Diagnostic Systems
Imberhorne Lane, East Grinstead
West Sussex, RH19 1QX
United Kingdom

DEVICES COVERED BY THIS DECLARATION:

- VersaTREK Automated Microbial Detection Systems listed below with
  - Mainboard Firmware Version 1.9.2, or higher
  - Software Version 5.2.8.9 with Version 5.2.8.9 SP3 (Service Pack 3), or higher
  - AT Board Firmware Version 1.3.1, or higher
  - Module Board Firmware Version 1.11.1, or higher
  - Software Language Kit
  - 6240-04-220 VersaTREK 240 with 4 Drawers, 220V
  - 6240-06-220 VersaTREK 240 with 6 Drawers, 220V
  - 6240-08-220 VersaTREK 240 with 8 Drawers, 220V
  - 6240-10-220 VersaTREK 240 with 10 Drawers, 220V
  - 6528-14-220 VersaTREK 240 with 14 Drawers, 220V
  - 6528-16-220 VersaTREK 240 with 16 Drawers, 220V
  - 6528-18-220 VersaTREK 240 with 18 Drawers, 220V
  - 6528-20-220 VersaTREK 240 with 20 Drawers, 220V
  - 6528-22-220 VersaTREK 240 with 22 Drawers, 220V

DECLARATION STATEMENT:

We hereby declare that the above-mentioned devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

DATE OF VALIDITY:

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after 28 November 2003 and which bear the CE marking.

AUTHORIZED SIGNATURE:

Teresa Anacker
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Teresa Anacker
Quality Assurance/Regulatory Affairs Manager
TREK Diagnostic Systems

Date: 19 July 2004