



HTZ

Declaration of Conformity

Manufacturers Name HTZ Ltd

Manufacturers Address:

Unit 4, The Felbridge Centre,
Imberhorne Lane,
East Grinstead,
West Sussex,
RH19 1XP
Tel: +44 1689 843345

Type of Equipment Sample Processor

Product Name Automation Blood Grouping Analyser System

Model Number BeeGroup 300

This is to certify that the above instrument conforms with the essential Requirements of the following Council Directives:-

- Electromagnetic Compatability Directive 89/336/EEC,
- Low Voltage Directive 73/23/EEC
- In Vitro Device Directive 98/79/EEC (Annex 111)

The following EMC standards have been applied during testing:

▪ Harmonic	EN 61000-3-2
▪ Flicker	EN 61000-3-3
▪ Immunity Test - ESD	EN 61000-4-2
▪ Radiated Immunity test	EN 61000-4-3
▪ Electrical fast transient/Burst immunity test	EN 61000-4-4
▪ Immunity Test - Conducted RF	EN 61000-4-6
▪ Immunity Test - Voltage Surges (AC Power Port)	EN61000-4-5
▪ Immunity Test – Voltage Dips & Interruptions	EN 61000-4-11
▪ Conducted & Radiated Emissions	EN 55022

The following product safety standards have been applied during testing:

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|-------------------------------|---------------------|
| • General Safety requirements | EN 61010-1:2001 |
| • IVD Safety requirements | EN 61010-2-101:2002 |

Signed

Full Name Neil Woodmansey

Position Company Director

Date April 2nd 2009