

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer
Model: BC-5300

Including reagents as following:

M-53LEO(I) LYSE

M-53LEO(II) LYSE

M-53LH LYSE

M-53D DILUENT

M-53 CLEANSER

M-53P PROBE CLEANSER

Classification: Others
Conformity Assessment Route: IVDD Annex

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Place, Date of Issue: Shenzhen, 2008-09-05

Signature:

Name of Authorized Signatory: Mr. Yang Long
Position Held in Company: Management Representative