Declaration of Conformity CE

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-5380** Including reagents as following: **M-53LEO(I) LYSE** **M-53LEO(II) LYSE** **M-53LH LYSE** **M-53D DILUENT** **M-53 CLEANSER** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation
Conformity Assessment Route:	IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Field repairable unit:

Field repairable units can be provided as attachment.

Start of CE-Marking:	**2008- 12- 29**
Place, Date of Issue:	Shenzhen, 2016-03-01
Signature:	
Name of Authorized Signatory:	Mr. Tan ChuanBin
Position Held in Company:	Manager ,Technical Regulation