Declaration of Conformity V 11.0

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-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: 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.

Start of CE-Marking: 2008-09-05

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: 谭传彬

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Digitally signed by Condrat Natalia
Date: 2019.04.26 09:02:55 EEST
Reason: MoldSign Signature
Location: Moldova