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:	**Hematology Calibrator**
Model:	**SC-CAL PLUS**
Applied Hematology Analyzer Model:	**BC-5500, BC-5200, BC-3200, BC-3000CT，BC-3000 Plus, BC-2800, BC-2600, BC-2900 BC-1800, BC-2300, BC-2100, BC-5300,BC-5100 BC-5380,BC-5180,BC-5800,BC-5600,BC-6800，BC-6600 BC-3600 ,BC-3300,BC-5000,BC-5150,BC-5120,BC-5130 BC-5140,BC-5390,BC-30s,BC-31s,BC-20s,BC-21s,BC-30 BC-31,BC-6000,BC-6100,BC-6000Plus,BC-6100Plus BC-6200,BC-6800Plus,BC-6700Plu,BC-6600Plus,BC-30e**
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 under our sole responsibility 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.

Digitally signed by Efremova Iulia
Date: 2019.11.01 14:44:41 EET
Reason: MoldSign Signature
Location: Moldova

Start of CE-Marking: 2009-06-05

Place, Date of Issue: Shenzhen, 2018-8-15

Signature: .....

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic reagents
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
ISO14971: 2012	Medical devices – Application of risk management to medical devices
ISO 17511: 2003	In vitro diagnostic medical device – Measurement of quantities in biological sample – Metrological traceability of values assigned to calibrator and control materials
ISO15194：2009	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation