EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 761396 R000

Manufacturer: Shenzhen Mindray Scientific Co., Ltd.

Address:
6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block
Guangming District
Shenzhen
Guangdong
518106
China

Single Registration Number: CN-MF-000030037

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestraße 80
20537 Hamburg
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-03**

Current Issue Date: **2023-08-11**

Starting Validity Date: **2023-08-11**

Expiry Date: **2028-01-02**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12– Administer and/or remove a medicinal substance	**Intended purpose**
Infusion pumps	The infusion pump is intended for use for the delivery of medications, solutions, nutrition, lipids, blood and blood components indicated for infusion therapy.
Syringe pumps	The syringe pump is intended for use on adults, paediatrics, and neonates for the intermittent or continuous delivery of medications, solutions, parenteral nutrition, lipids indicated for infusion therapy through an intravenous or intra-arterial routes.

Class IIb	**Intended purpose**
INFUSION AND SYRINGE PUMP CONTROL SYSTEMS	The device is intended for conjunction with the infusion pump and syringe pump, providing space management, power management, alarm management, information display, and communicate with pump to transmit data.

Device(s)	**Risk Classification**
Gravity infusion monitor	Class Im
Output monitor	Class Im
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-03	3577341	Issued
2023-07-20	30002446	Supplemented - Addition of INFUSION AND SYRINGE PUMP CONTROL SYSTEMS.
Current	30005561	Supplemented - Addition of Gravity infusion monitor and Output monitor.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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