EU Quality Management System Certificate

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

MDR 761396

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 and Class IIb implantable devices an 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: **2023-01-03**

Starting Validity Date: **2023-01-03**

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 pump	The infusion pump is intended for use for the delivery of medications, solutions, nutrition, lipids, blood and blood components indicated for infusion therapy.
Syringe pump	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.

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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
Current	3577341	Issued

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.