EU Quality Management System Certificate

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

MDR 781315 R000

Manufacturer: PMH - Produtos Médicos Hospitalares, SA

Address:
Zona Industrial da Murteira
Rua da Guiné Bissau, Lote 9
2135-327 Samora Correia
Portugal

Single Registration Number: PT-MF-000007631

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 Global Regulatory & Quality

First Issue Date: **2024-11-13**

Current Issue Date: **2024-11-13**

Starting Validity Date: **2024-11-13**

Expiry Date: **2029-11-12**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cannulas and tips for aspiration	Class IIa
Blood administration sets	Class IIa
Extension and infusion sets and connectors	Class IIa
Connectors and adaptors for infusion sets such as spikes, transfers spike and connector, valves	Class IIa
Irrigation sets	Class Is
Aspiration tubes and drainage systems	Class Is
Urine collection systems and bags	Class Is
Caps	Class Is
Enteral feeding lines, sets and adaptors	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. 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. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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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	3793250	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.
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