



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

PMH - Produtos Médicos Hospitalares,S.A. Zona Industrial da Murteira Rua da Guiné Bissau, Lote 9 2135-327 Samora Correia Portugal

Holds Certificate Number:

MD 651759

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of sterile intravenous solution administration sets and extension sets, blood administration sets, aspiration cannula, valves and stopcocks, spikes and transfer spikes, urine collection systems and bags, aspiration and drainage systems, aspiration tubes and caps, enteral feeding lines, sets and adapters, and irrigation sets. Non-sterile urine collection systems and bags, aspiration and drainage systems, and aspiration tubes.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-06-30 Latest Revision Date: 2025-06-19

bsi.



Effective Date: 2025-06-30 Expiry Date: 2028-06-29

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 651759

Location

PMH - Produtos Médicos Hospitalares SA Zona Industrial da Murteira Rua da Guiné Bissau, Lote 9 2135-327 Samora Correia Portugal

PMH - Produtos Médicos Hospitalares, SA Zona Industrial 1 Guilhufe Penafiel 4560-164 Portugal **Registered Activities**

Design and manufacture of sterile intravenous solution administration sets and extension sets, blood administration sets, aspiration cannula, valves and stopcocks, spikes and transfer spikes, urine collection systems and bags, aspiration and drainage systems, aspiration tubes and caps, enteral feeding lines, sets and adapters, and irrigation sets. Nonsterile urine collection systems and bags, aspiration and drainage systems, and aspiration tubes.

Manufacture of sterile intravenous solution administration sets and extension sets, blood administration sets, aspiration cannula, valves and stopcocks, spikes and transfer spikes, urine collection systems and bags, aspiration and drainage systems, aspiration tubes and caps, enteral feeding lines, sets and adapters, and irrigation sets. Non-sterile urine collection systems and bags, aspiration and drainage systems, and aspiration tubes.

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