By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 651772**

Issued To: **PMH - Produtos Medico Hospitalares, SA**
Zona Industrial da Murteira
Lote 9, Porto Alto
Samora Correia
2135-311
Portugal

In respect of:

Manufacture and final inspection of sterile intravenous solution administration sets and extension sets, sterile valves and stopcocks, sterile blood administration sets and sterile aspiration cannula.
Those aspect of Annex V concerned with securing and maintaining sterile conditions of intravenous administration sets and extension sets, high flow sets, valves and stopcocks, spikes and transfer spikes, urine drainage bags, aspiration and drainage systems, enteric systems, aspiration tubes and caps.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-30** Date: **2020-05-19** Expiry Date: **2024-05-26**

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Supplementary Information to CE 651772

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Intravenous solution administration sets for pumps (non-invasive)	N/A
MD 0102	Blood administration sets	N/A
MD 0102	Extension sets (IV set used with pump)	N/A
MD 0106	Aspiration cannulas	N/A
Class Is		
MD 0102	Intravenous solution administration sets (by gravity)	N/A
MD 0102	High flow sets	N/A
MD 0102	Extension sets (by gravity)	N/A
MD 0101	Urine drainage bag	N/A
MD 0106	Aspiration and drainage systems	N/A
MD 0106	Aspiration Tubes	N/A
MD 0102	Spikes	N/A
MD 0102	Transfer Spikes	N/A
MD 0102	Caps	N/A

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Number	Device Name	Intended purpose per IFU
MD 0102	Valves	N/A
MD 0102	Enteric Systems	N/A

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 651772**
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Subcontractor:	**Service(s) supplied**
PMH - Produtos Medico Hospitalares, SA Zona Industrial 1 Guilhufe Penafiel 4560-164 Portugal	**ETO Sterilization** **Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 651772**

Date: **2020-05-19**

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Date	Reference Number	Action
30 June 2016	8503005	First issue.
16 August 2016	8574951	Addition of intravenous solution administration sets and extension sets, valves and stopcocks, blood administration sets and aspiration cannula.
01 March 2019	8593574	Traceable to NB 0086.
Current	3166852	Certificate Renewal. Inclusion of product tables. Scope reduction (removal of Guedel airways)