

# 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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 651772

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
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
<b>Class Is</b>		
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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

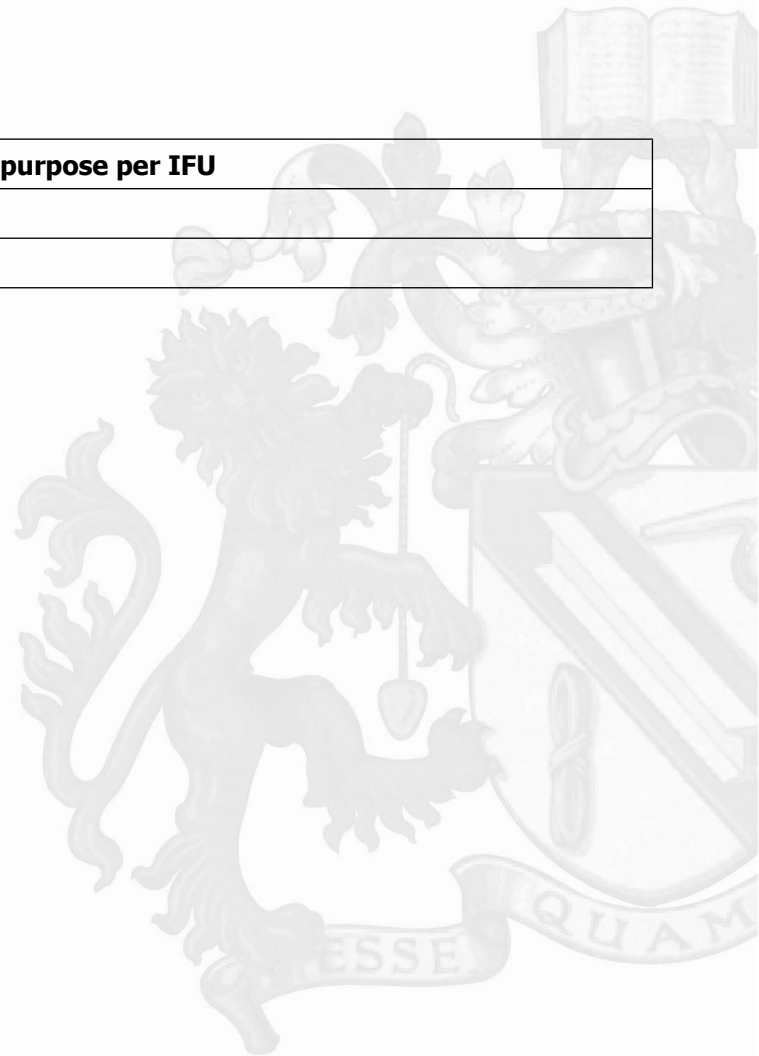
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Number	Device Name	Intended purpose per IFU
MD 0102	Valves	N/A
MD 0102	Enteric Systems	N/A



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## List of Significant Subcontractors

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

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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)

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