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

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