

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 650642
Issued To: **Pacific Hospital Supply Co., Ltd.**
4F
No. 160, Daye Rd.
Beitou Dist.
Taipei City
11268
Taiwan

In respect of:

Design and Development, Manufacture of sterile and non-sterile Body Waste Collection Systems, and Medical Irrigation, Suction and Drainage Systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **25 August 2016**

Date: **25 August 2016**

Expiry Date: **22 August 2021**

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
mdi Europa GmbH Langenhagener Str. 71 Langenhagen 30855 Germany	EU Representative
Pacific Hospital Supply Co., Ltd. Head Plant No. 19, Tzi Chiang Rd. Torng-Lo Ind. District Miaoli County 36642 Taiwan	Manufacture Sterilization
Pacific Hospital Supply Co., Ltd. Plant 1 No. 6, Ming Chyr Rd. Torng-Lo Ind. District Miaoli County 36645 Taiwan	Manufacture Sterilization

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Subcontractor:

Service(s) supplied

Pacific Hospital Supply Co., Ltd.
Plant 3
No. 16, Ming Shen Rd.
Torng-Lo Ind. District
Miaoli County
36646
Taiwan

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 650642
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Date	Reference Number	Action
25 August 2016	8498093	Transfer from another notified body. Certificate Renewal.