



DNV BUSINESS ASSURANCE

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 31193-2008-AQ-RGC-NA

This is to certify that the Management System of:

Pacific Hospital Supply Co., Ltd.

4F, No. 160, Daye Rd., Beitou District, 112 Taipei, Taiwan

has been found to conform to the standard:

ISO 13485:2003

This Certificate is valid for the following product or service ranges:

Design and Manufacture of Medical Suction and Drainage Systems, Body Waste Collection Systems, Urinary Drainage Bags, Breathing Circuit Devices, General and Surgical Instruments and Accessories, Anesthetic And Respiratory Equipment, and Infusion Devices.

**The Validation and Routine Control of Ethylene Oxide Sterilization
Complied with the latest edition of EN ISO 11135-1:2007 Requirements.**

**The Design, Manufacture, and Process Validation for Sterile Packaging Complied with
the latest edition of EN ISO 11607-1:2009 and EN ISO 11607-2:2006 Requirements.**

Initial Certification date:

28 April 2001

This Certificate is valid until:

15 July 2018

*The audit has been performed under the
supervision of*

Frances Leu
Lead Auditor



Place and date:

Høvik, 26 June 2015

for the Accredited Unit:
DNV GL Business Assurance
Norway AS.

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

HEAD OFFICE, Det Norske Veritas AS, Veritasveien 1, 1322 Hovik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 - www.dnv.com



DNV BUSINESS ASSURANCE

APPENDIX TO CERTIFICATE

This Appendix refers to Certificate No. 31193-2008-AQ-RGC-NA

Pacific Hospital Supply Co., Ltd.

locations included in the certification are as follows:

Site Name	Site address	Function
Head Quarter Manufacture Office	4F, No.160, Daye Rd., Beitou District, Taipei 112, Taiwan	Management, Sales, Design, Purchasing, HR, RA (regulatory affair)
Main PLANT	No. 19, Tzi Chiang Rd., Torng-Lo Ind. District, Miaoli 366, Taiwan	QC, QA, Manufacturing, Warehouse, HR, DCC
1 st PLANT	No. 6, Ming Chyr Rd., Torng-Lo Ind. District, Miaoli 366, Taiwan	QC, QA, Manufacturing, Warehouse, HR
3 RD PLANT	No. 16, Ming Shen Rd., Torng-Lo Ind. District, Miaoli 366, Taiwan	Warehouse

Initial Certification date:

28 April 2001

This Certificate is valid until:

15 July 2018

*The audit has been performed under the
supervision of*

Frances Leu
Lead Auditor



Place and date:

Høvik, 26 June 2015

for the Accredited Unit:

DNV GL Business Assurance
Norway AS.

Eugenie Winger Husebye
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info