

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
217313-2017-AQ-RGC-NA-PS

Initial certification date:
28 April 2001

Valid:
16 July 2024 – 15 July 2027

This is to certify that the management system of
Pacific Hospital Supply Co., Ltd.
4F, No.160, Daye Road, Beitou District, Taipei 112, Taiwan
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacture, Sales and Distribution of Sterile Medical Irrigation, Suction and Drainage Systems, Body Waste Collection Systems, Urinary Drainage Bags, General and Surgical Instruments and Accessories.

Design, Manufacture, Sales, Servicing and Distribution of Anesthetic and Respiratory Equipment, Breathing Circuit Devices, and Infusion Devices.

The Development, Validation and Routine Control of Ethylene Oxide Sterilization Process as per ISO 11135: 2014/ EN ISO 11135:2014 /A1:2019 Requirements.

The Design, Manufacture and Process Validation for Sterile Packaging System as per ISO 11607-1: 2019/EN ISO 11607-1:2020 and ISO 11607-2: 2019/ EN ISO 11607-2:2020 Requirements.

Place and date:
Høvik, 08 June 2024



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Appendix to Certificate

Pacific Hospital Supply Co., Ltd.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Pacific Hospital Supply Co., Ltd.	4F, No.160, Daye Road, Beitou District, Taipei 112, Taiwan	Design and Sales of Sterile Medical Irrigation, Suction and Drainage Systems, Body Waste Collection Systems, Urinary Drainage Bags, General and Surgical Instruments and Accessories. Design and Sales of Sterile and Non-Sterile Anesthetic and Respiratory Equipment, Breathing Circuit Devices, and Infusion Devices.
Pacific Hospital Supply Co., Ltd.	No. 8, Tongke 2nd Rd , Tongluo Township, Miaoli 366, Taiwan	Manufacture and Distribution of Sterile Medical Irrigation, Suction and Drainage Systems, Body Waste Collection Systems, Urinary Drainage Bags, Breathing Circuit Devices, General and Surgical Instruments and Accessories and Infusion Devices. Manufacture, Servicing and Distribution of Sterile and Non-Sterile Anesthetic and Respiratory Equipment, Breathing Circuit Devices, and Infusion Devices. The Development, Validation and Routine Control of Ethylene Oxide Sterilization Process as per ISO 11135: 2014/ EN ISO 11135:2014 /A1:2019 Requirements. The Design, Manufacture and Process Validation for Sterile Packaging System as per ISO 11607-1: 2019/EN ISO 11607-1:2020 and ISO 11607-2: 2019/ EN ISO 11607-2:2020 Requirements.