

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 248771-2017-AQ-RGC-NA-PS Rev.3.0

Initial certification date: 19 November 2004

Valid: 25 February 2022 – 24 February 2025

This is to certify that the management system of

Cenefom Corp.

2F. & 3F., No. 50-3, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, 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 and Non-sterile Medical Sponge for Ophthalmic, E.N.T. and General Surgery.

Manufacture and Sales of Sterile and Non-sterile Dressing Products for Wound Treatment.

Place and date: Høvik, 27 December 2021



For the issuing office: DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway

Ceulie Gudesen Torp

Cecilie Gudesen Torp Management Representative





Certificate no.: 248771-2017-AQ-RGC-NA-PS Rev.3.0 Place and date: Høvik, 27 December 2021

Appendix to Certificate

Cenefom Corp.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Cenefom Corp.	2F. & 3F., No. 50-3, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, Taiwan	Design and Manufacture of Sterile and Non-sterile Medical Sponge for Ophthalmic, E.N.T. and General Surgery. Manufacture of Sterile and Non-sterile Dressing Products for Wound Treatment.
Cenefom Corp. (Head office)	1F., No. 50-5, Keyan Rd., Hsinchu Science Park, Zhunan Township, Miaoli County 35053, Taiwan	Design, Sales and Distribution of Sterile and Non-sterile Medical Sponge for Ophthalmic, E.N.T. and General Surgery. Sales of Sterile and Non-sterile Dressing Products for Wound Treatment.

