



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
242366-2017-AQ-TWN-NA-PS

Initial certification date:  
06 September 2017

Valid:  
28 February 2025 – 27 February 2028

This is to certify that the management system of  
**ONYX Healthcare Inc.**  
4F., No. 135, Ln. 235, Baoqiao Rd., Xindian Dist., New Taipei City 231028, 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**

This certificate is valid for the following scope:

**Design, Development, Manufacture, Sales, Servicing and Distribution of Computer and Display for Diagnostic Medical Devices.  
Manufacture and Servicing of Clinical Chemistry Analyzer and Accessories.**

Place and date:  
Høvik, 12 February 2025



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

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Management Representative



Certificate no.: 242366-2017-AQ-TWN-NA-PS  
Place and date: Høvik, 12 February 2025

## Appendix to Certificate

### ONYX Healthcare Inc.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
ONYX Healthcare Inc.	4F., No. 135, Ln. 235, Baoqiao Rd., Xindian Dist., New Taipei City 231028, Taiwan	Design, Development, Manufacture, Sales, Servicing and Distribution of Computer and Display for Diagnostic Medical Devices. Manufacture and Servicing of Clinical Chemistry Analyzer and Accessories.
ONYX Healthcare Inc. Hsinchu Factory	3F, No. 480, Nioupu E. Rd., Hsinchu, Taiwan	Manufacture of Computer and Display for Diagnostic Medical Devices.
ONYX Healthcare USA, Inc.	324 West Blueridge Avenue, Orange, CA, 92865, USA	Sales, Servicing and Distribution of Computer and Display for Diagnostic Medical Devices.

