



# MANAGEMENT SYSTEM CERTIFICATE

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

Initial certification date:  
06 September 2017

Valid:  
10 January 2023 – 27 February 2025

This is to certify that the management system of

## **ONYX Healthcare Inc.**

2F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien Dist., New Taipei City 231, 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, Manufacture, Sales, Return Material Authorization and Distribution of Computer  
and Display for Diagnostic Medical Devices.**

Place and date:  
Høvik, 10 January 2023



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, 10 January 2023

## Appendix to Certificate

### ONYX Healthcare Inc.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
ONYX Healthcare Inc.	2F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien Dist., New Taipei City 231, Taiwan	Design, Manufacture, Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.
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, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.

