



# Management System Certificate

Certificate No.:  
242366-2017-AQ-RGC-NA-PS Rev. 1.0

Project No.:  
PRJC-308157-2011-MS-C-TWN

Initial Certification Date:  
06 September 2017

Valid Until:  
27 February 2022

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

With sites as listed overleaf.

Complies with the requirements of:

## **ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, Assembly, Sales, Return Material Authorization and Distribution of  
Computer and Display for Diagnostic Medical Devices.**

Place and Date:  
Høvik, 28 February 2019



For:  
DNV GL PRESAFE AS

*Tone Kolpus*

**Tone Elise Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info



The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

DNV GL PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA

Page 1 of 2



# Management System Certificate

Certificate No.:  
242366-2017-AQ-RGC-NA-PS Rev. 1.0

Project No.:  
PRJC-308157-2011-MS-C-TWN

Initial Certification Date:  
06 September 2017

Valid Until:  
27 February 2022

Site Name	Address	Site Scope
ONYX Healthcare Inc. (Taipei Headquarters)	2F, No. 135, Lane 235, Pao Chiao Rd.,231,New Taipei City,Taiwan	Design, Assembly, Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.  Activities: PM, Sales, Design, Procurement, Manufacturing ,QC, Return Material Authorization, Warehouse
ONYX Healthcare USA, Inc. (USA Branch office)	324 West Blueridge Avenue,92865,Orange,USA	Sales, Return Material Authorization and Distribution of Computer and Display for Diagnostic Medical Devices.  Activities: Sales, Return Material Authorization, Warehouse

End of Certificate