



Certificate TW10/00615.00

The management system of

# Abnova (Taiwan) Corporation

9th Fl., No. 108, Jhouzih St., Neihu District,  
Taipei City, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 20 November 2018 until 20 November 2021 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 04 October 2021  
Issue 9. Certified since 18 November 2010

Multiple certificates have been issued for this scope  
The main certificate is numbered TW10/00615.00

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd  
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# Abnova (Taiwan) Corporation

## ISO 13485:2016 EN ISO 13485:2016

Issue 9

Detailed scope



**Design, Manufacture and Sales of IVD (*in vitro* diagnostic) Products.**

**Products Category:**

- 1. Immunohistochemistry Reagents and Kits.**
- 2. FISH (Fluorescence *In Situ* Hybridization) Probes**
- 3. ELISA (Enzyme-Linked Immunosorbent Assay) Kits.**
- 4. Rapid Test Kits**
- 5. Antibodies and kits for Cell Antigens**
- 6. Instruments for Cell Separation.**
- 7. Chips for Cell Separation.**

Additional facilities

**9th Fl., No. 112 & 114, Jhouzih St., Neihu District,  
Taipei City, Taiwan, R.O.C.**

**No. 326-8, Sec. 4, Zhongzheng Rd., Zhongli Dist.,  
Taoyuan City 320, Taiwan, R.O.C.**



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