



Certificate TW10/00615.00

The management system of

Abnova (Taiwan) Corporation

9th Fl., No. 108, Jhouzih St., Neihsu 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

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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., Neihs 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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