



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 2021 until 20 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 11. 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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SGS United Kingdom Ltd
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Abnova (Taiwan) Corporation

ISO 13485:2016 EN ISO 13485:2016

Issue 11



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 and Kits.
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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