



Certificate

No. Q5 068838 0005 Rev. 03

Holder of Certificate: ALLEN HEALTHCARE PRODUCTS (M) SDN. BHD.

No.17, Lorong Nagasari 2
Taman Nagasari
13600 Perai, Penang
MALAYSIA

Facility(ies):

ALLEN HEALTHCARE PRODUCTS (M) SDN. BHD.
No.17, Lorong Nagasari 2, Taman Nagasari, 13600 Perai,
Penang, MALAYSIA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and Development, Manufacturing and Distribution of In-Vitro Diagnostic Test Kits (hCG Pregnancy Test, Drug Abuse Test Kits, Dengue Test Kits, Malaria Test Kits, Syphilis Test Kits, Hepatitis C Test Kits, Hepatitis B Test Kits and HIV Test Kits)

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 068838 0005 Rev. 03

Report No.: 5598687-721429684

Valid from: 2022-08-24

Valid until: 2025-08-23

Date, 2022-05-17



Christoph Dicks

Head of Certification/Notified Body