



Company Profile

TS Diagnostics is a manufacturer specializing in in-vitro diagnostics test kits and reagents. Our manufacturing facility has received the ISO13485:2016 certification, making our facilities on par with the highest standard manufacturers around the world.

Strategically located in the middle of ASEAN region, we are able to engage and meet the requirements of our customers around the world in a timely and cost-efficient manner, providing quality products at competitive prices.

For many years, our bestselling core products are the Forsure Pregnancy Test and Forsure Urine Drug Test and the other rapid test kits range. Now stepping into our 2nd phase of expansion, we have established in-house R&D expert and our facilities are upgraded and equipped to manufacture high quality reagents covering the discipline of hematology, microbiology and serology.

TS Diagnostics is also an expert in consulting, creating and supplying private labels to major retailers in the region.

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|-------------------------------------|---|
| Company name | TS Diagnostics Sdn Bhd |
| Company registration number | 896280-D |
| Year established | 2010 |
| Factory & office address | No. 7 & 9, Jalan TPP 5/11 Taman Perindustrian Puchong 47160 Selangor, Malaysia |
| Telephone number | +60.3.8068.7311 |
| Facsimile number | +60.3.8051.1778 |
| Email address | contactus@ts-diagnostics.com |
| Website | www.forsure-test.com / www.bio-test.info |
| Management | Mr. Tang Boon Huan (Chief Executive Officer) Dr. Fawwaz al-Joudi (Head of R & D) Ms. Joyce Tang (Head of QMS Division) Ms. Jess Yap (Head of Business Division) |
| Quality Management System | <ul style="list-style-type: none"> • ISO13485:2016 • GDPMD (Good Distribution Practice for Medical Devices) |
| Principle Activities | <ul style="list-style-type: none"> • Design & Development & Manufacturing of IVD Test • Marketing & Distribution of Medical Devices • Private Label specialist in IVD Test |

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|----------------------|--|
| Product Range | <ul style="list-style-type: none"> • Rapid Test Kit (Fertility, Urine Drug, Infectious Diseases both Antigen & Antibody, Cardiac Markers, Cancer Markers) • Urine Reagent Strips • Latex Kits • Febrile Antigens • Blood Grouping Reagents • Viral Transport Media |
| Vision | To be the Major Supplier of In-Vitro Diagnostic test kits in the global market |
| Mission | To deliver quality and cost-effective products through excellent customer service, quality management and efficient product realization system. |

Quality Policy

TS Diagnostics is committed to manufacturing quality medical devices in line with ISO13485 and applicable regulatory requirements, whilst ensuring fulfilment of customers' requirements and satisfaction.

Our Brand

Our QMS Certificates

CERTIFICATE

This is to certify that

TS Diagnostics Sdn. Bhd.
No. 7 & 8, Jalan TPF 5/11,
 Taman Perindustrian Puchong,
 47160 Puchong, Selangor,
 Malaysia.

has implemented and maintains a **Quality Management System**.

Scope:
 Design and Development, Manufacturing and Distribution of IVD Rapid Tests, Blood Grouping Reagents and Latex Kits.
 Manufacturing and Distribution of Urine Reagent Strips, Febrile Antigens Reagents.

Through an audit, documented in a report, it was verified that the management system fulfils the requirements of the following standard:

ISO 13485 : 2016

Certificate registration no. 498759 MP2016

Date of certification 2021-01-15

Valid until 2024-01-14

DQS Certification (M) Sdn Bhd

Darry Ng
Regional Managing Director

Accredited Body: DQS MALAYSIA, Suite 43-44, 56th Avenue, Jalan Datta Priya D U 13/2, 56100 Alam Sekeloa U 13, 48170 Shah Alam, Selangor - Malaysia

CERTIFICATE

This is to certify that

TS Diagnostics Sdn. Bhd.
No. 7 & 8, Jalan TPF 5/11,
 Taman Perindustrian Puchong,
 47160 Puchong, Selangor,
 Malaysia.

has implemented and maintains a **Good Distribution Practice For Medical Devices**.

Scope:
 Local Authorised Representative, Import, Storage & Handling, Warehousing, Secondary Assembly, Distribution and Documentation of In-Vitro Diagnostic Kits and Reagents for Agglutination Tests in Latex-based Reagents, Febrile Antigens & Blood Grouping Reagents.

Through an audit, documented in a report, it was verified that the management system fulfils the requirements of the following standard:

GDPM (Edition: 1st November 2015)

Certificate registration no. 498759 GDPM

Date of certification 2021-01-15

Valid until 2024-01-14

DQS Certification (M) Sdn Bhd

Darry Ng
Regional Managing Director

Conformity Assessment Body: DQS Certification (M) Sdn Bhd (MCA-CAB-2061), Suite 43-44, 56th Avenue, Jalan Datta Priya D U 13/2, 56100 Alam Sekeloa U 13, 48170 Shah Alam, Selangor, Malaysia