

Certificate

Standard

**Quality Management System
ISO 13485:2016**

Certificate Number

SX 2058691-1

TUV Rheinland Malaysia Sdn. Bhd. certifies:

Certificate Holder:

**Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 Shah Alam, Selangor Darul Ehsan,
Malaysia**

The Certification Body of TÜV Rheinland Malaysia Sdn. Bhd. certifies that the organization has established and applies a quality management system for medical devices in accordance to ISO 13485:2016 standard pursuant to Appendix 4, Third Schedule of Medical Device Regulations 2012.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subjected to yearly surveillance.

Scope:

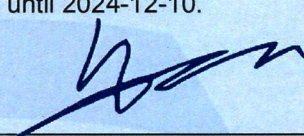
Manufacture and Distribution of Thermal Paper Recording for Electrocardiography (ECG), Cardiotocography (CTG) and Ultrasound. Distribution of Ultrasound Transmission Gels.

Validity:

The certificate is valid from 2022-12-09 until 2024-12-10.



2023-04-28


TUV Rheinland Malaysia Sdn. Bhd.
Shah Alam, Selangor, Malaysia
MDA/CAB-007

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2058691-1

Organization: Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 Shah Alam, Selangor Darul Ehsan,
Malaysia

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Tele-Paper (M) Sdn. Bhd. Lot 2C, Jalan Keluli 15/16, Section 15, 40200 Shah Alam, Selangor Darul Ehsan, Malaysia	Distribution of Thermal Paper Recording for Electrocardiography (ECG), Cardiotocography (CTG) and Ultrasound. Distribution of Ultrasound Transmission Gels.
/02	c/o Tele-Paper (M) Sdn Bhd Lot No. 1, Jalan Sejahtera 25/124, Axis Premier Industrial Park, Taman Sri Muda, Section 25, 40400 Shah Alam, Selangor Malaysia	Manufacture and Distribution of Thermal Paper Recording for Electrocardiography (ECG), Cardiotocography (CTG) and Ultrasound.

Report No.: 250112721-21
Effective date: 2022-12-09
Expiry date: 2024-12-10
Issue date: 2023-04-28



Ryo Furukawa
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2058691-1

Organization: Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 Shah Alam, Selangor Darul Ehsan,
Malaysia

Scope: Manufacture and Distribution of Thermal Paper Recording for
Electrocardiography (ECG), Cardiotocography (CTG) and Ultrasound.
Distribution of Ultrasound Transmission Gels.

A large, faint, light blue version of the TÜV Rheinland logo is centered in the background of the certificate.
TÜVRheinland®

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 250112721-21
Effective date: 2022-12-09
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Ryo Furukawa

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