

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.

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.: 250110197-32

Effective date: 2021-12-22

Expiry date: 2022-12-10

Issue date: 2021-12-22



Ning Chang

Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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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.

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QUALITY SYSTEM CERTIFICATE

This is to Certify that the Quality Management System of

SKYLER BIOTECH SDN. BHD. (1206111-T)

No. 26, Jalan TPP 1/16,
Taman Perindustrian Puchong,
47160 Puchong, Selangor Darul Ehsan,
Malaysia

has been assessed by **KGS** Certification Sdn. Bhd.
and found to comply with

ISO 13485:2016

Medical Devices Quality Management System

for the scope

Manufacturing of Ultrasound Gel, ECG Gel and Lubricant Gel

Certificate No : **510180**
Date of Initial Certification : **28 September 2018**
Date of Issue/Reissue : **02 August 2021**
Renewal Due : **27 September 2024**



MDQMS 15102014 CB 01




Authorized Signatory

This certificate is subject to the company maintaining its system to the required standards, which will be monitored by KGS. The use of this Certificate and the KGS Certification / Accreditation Mark are subject to the Regulations Applicable to Holders of KGS Certification Sdn. Bhd.

KGS Certification Sdn. Bhd. (824092-A)

No. 15, BLM 5/4, Laguna Merbok, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.
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www.kgscert.com

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