

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2058691-1
Certificate Holder: Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 Shah Alam, Selangor Darul Ehsan,
Malaysia

Scope: Design & Development, Manufacture and Distribution of
Thermal Paper Recording for Electrocardiography (ECG) and
Cardiotocography (CTG).
Manufacture and Distribution of Medical Gel (Ultrasound Gel
and ECG Gel) and Ultrasound paper.
Distribution of Cooling Gel Patch.

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.: 250116506-21
Effective date: 2024-12-11
Expiry date: 2027-12-10
Issue date: 2024-10-10
Replaces certificate SX 2058691-1 issued 2023-04-28

Furukawa Ryo

Ryo Furukawa
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This certificate can be validated on <https://www.certipedia.com>

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The scope of certification also covers the following sites:

| 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 | Design & Development, Distribution of Thermal Paper Recording for Electrocardiography (ECG) and Cardiotocography (CTG). Distribution of Medical Gel (Ultrasound Gel and ECG Gel) and Ultrasound paper. Distribution of Cooling Gel Patch. |
| /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) and Cardiotocography (CTG) and Ultrasound paper. |

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