

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60147888 0001

Report No.: 12031245 009

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

Products: Aspects of manufacture concerned with the conformity of
Thermal Paper Recording for ECG with Ultrasound with
the metrological requirements

Replaces Approval, Registration No.: DD 60134837 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-05-24

Date: 2020-05-24



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH

Confirmation Letter

2022-03-07

To whom it may concern,

With this letter we confirm the following:

Company name: Tele-Paper (M) Sdn. Bhd.

Address: Lot 2C, Jalan Keluli 15/16 Section 15, Shah Alam 40200 Selangor Malaysia

Has applied with TÜV Rheinland LGA Products GmbH (TRLP) MDD 93/42/EEC. According to Product List and Application submitted in Year 2018, the list includes Paper Recording CTG, however, this product was omitted from the existing issued MDD 93/42/EEC certificate <Cert No.: DD 60147888 0001>. Based on recent years Sampling Plan, this Paper Recording CTG was never been sampled for Technical Documentation review. Technical Documentation of Paper Recording CTG Paper was reviewed in Year 2021 with respect to the recent Significant Change Notification for EN ISO 13485:2016 audit scope. It was confirmed that the CTG Paper contains measuring function. The Organization implements and maintains a quality management system in accordance with the requirements of and MDD 93/42/EEC Annex V for the below aspects:

Scope: Aspects of manufacture concerned with the conformity of Thermal Paper Recording for ECG and CTG with Ultrasound with the metrological requirements.

History of Product List and Applications: 2022-01-28

Product List and Applications signed: 2021-04-24

Expiry date: 2024-05-26

Kind regards



Certification body

TÜV Rheinland LGA Products GmbH

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Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 SHAH ALAM, SELANGOR DARUL EHSAN,
MALAYSIA

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date July 02, 2024

Notified Body Confirmation Letter

Reference. : TELEP_MDR Application_2024-07-02; order # 250116457

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Tele-Paper (M) Sdn. Bhd.
Lot 2C, Jalan Keluli 15/16, Section 15,
40200 SHAH ALAM, SELANGOR DARUL EHSAN,
MALAYSIA
SRN Number: MY-MF-000041774

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer’s continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

On behalf of the Notified Body



Michiaki Aihara
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Paper Recording ECG	Class Im, Rule 1	N/A	DD 60147888 0001 NB# 0197
Paper Recording CTG	Class Im, Rule 1	N/A	DD 60147888 0001 NB# 0197
Paper Photographic	Class Im, Rule 1	N/A	DD 60147888 0001 NB# 0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/07-02	TELEP_CL607_2024-07-02	Initial issue