



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

**Registration No.:** DD 60087278 0001

**Report No.:** 18501225 001

**Manufacturer:** Telepaper (M) Sdn. Bhd  
Lot No. 1, Jalan Sejahtera 25/124  
Axis Premier  
Industrial Park, Section 25,  
40400 Shah Alam, Selangor, Darul Ehsan  
Malaysia



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

**Expiry Date:** 2018-04-29

CHONG YOUN SIN  
NOTARY PUBLIC  
KLANG SELANGOR  
PN/WKL/HQ/25/39/97

12 JUL 2017

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:** 2013-08-02

**Date:** 2013-08-02



**Notified Body**

Dipl.-Ing. O. Masur

**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 0187

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth Certificate is that of Chong Youn Sin who is a Notary Public

The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.



ZULKIPLY ENDUT  
Consular Officer  
Consular Division  
Ministry of Foreign Affairs  
Putrajaya Malaysia

12 JUL 2017



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

Registration No.: DD 8008238 0001

Report No.: 1850225 001

Manufacturer:  
Tatpagar (M) Sdn Bhd  
Lot No. 1, Jalan Selatun 28124  
Axi Premier  
Industrial Park, Btong 28,  
80400 Shah Alam, Selangor, Darul Ehsan  
Malaysia



Product:  
Agents of medical devices covered by the certificate of  
Product Registration for DD 8008238 0001 and 1850225 001  
Medical devices

15 JUL 2017

Handwritten signature and stamp of the Ministry of Health of the Republic of Vietnam

The requirements of Annex V of the Directive 93/42/EEC have  
been stated in the certificate and are subject to a quality  
control system, defined by Annex V, section 4 of the  
Directive, in case it is not covered by the  
requirements of Annex V, section 4 of the  
Directive.

Medical Body




Unit GmbH - Tillystraße 2 - 80431 München

This is to certify that the signature  
of the official in the certificate is true and  
correct. The official is authorized to  
sign in the name of the Ministry of Health  
of the Republic of Vietnam. The Ministry  
of Health of the Republic of Vietnam is not  
responsible for the accuracy of the information  
contained therein.

Ministry of Health of the Republic of Vietnam  
Consulate General  
Consulate District  
Ministry of Health of the Republic of Vietnam  
Foreign Affairs





**ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM  
TẠI MA-LAI-XI-A**

**CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION**

1. Quốc gia .....  
Country ..... Việt Nam

2. do Ông (Bà) ..... ký  
has been signed by ..... Giấy tờ, tài liệu này  
This public document  
Zulkipty Endut

3. với chức danh ..... Lãnh sự  
acting in the capacity of ..... Cục Lãnh sự, Bộ Ngoại giao Ma-lai-xi-a

4. và con dấu của .....  
bears the seal/stamp of ..... Cục Lãnh sự, Bộ Ngoại giao Ma-lai-xi-a


được chứng nhận / hợp pháp hóa lãnh sự  
Certified

5. tại ..... Ma-lai-xi-a ..... 6. ngày ..... 20 / 7 / 2017  
at ..... the

7. Cơ quan cấp ..... Đại sứ quán nước CHXHCN Việt Nam  
by ..... Cục Lãnh sự, Bộ Ngoại giao Ma-lai-xi-a

8. Số ..... 632 / 2017  
№

Ký tên và đóng dấu  
Signature and Seal/stamp  
Tham tán Công sứ

  
Tôn Thị Ngọc Hương