

Certificate TW18/20003

The management system of

# Compal Electronics Inc.



No. 581 & 581-1, Ruiguang Rd., Neihu Dist., Taipei City, Taiwan (R.O.C.)

has been assessed and certified as meeting the requirements of

**ISO 13485:2016/EN ISO 13485:2016**

## **Medical devices - Quality management systems - Requirements for regulatory purposes**

For the following activities

1. Manufacture of Wireless sleep monitoring system for sleep management, Electroencephalography Amplifier and diagnostic ultrasound system.
2. Design and manufacture of Goniometer for the reference of rehabilitation, Ventilator, Radiofrequency Ablation Generator and Electrode Kit (Sterile Monopolar Electrode and Non-Sterile Neutral Electrode).
3. Design and manufacture of Medical image management and processing software.
4. Design and manufacture of Hearing aid.

This certificate is valid from 07 April 2026 until 09 March 2027 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 09 March 2018

Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

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Certificate TW18/20003, continued

# Compal Electronics Inc.

ISO 13485:2016/EN ISO 13485:2016

## Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 8

### Sites

Compal Electronics Inc.

No. 581 & 581-1, Ruiguang Rd., Neihu Dist., Taipei City, Taiwan (R.O.C.)

1. HR, Sales, IT and Management in support of Wireless sleep monitoring system for sleep management, Electroencephalography Amplifier and diagnostic ultrasound system.
2. Design of Goniometer for the reference of rehabilitation, Ventilator, Radiofrequency Ablation Generator and Electrode Kit (Sterile Monopolar Electrode and Non-Sterile Neutral Electrode).
3. Design of Medical image management and processing software.
4. Design of Hearing aid.

Compal Electronics Inc.

1、 2、 3、 4、 5F No.8-1 & 1、 2F No.8, Nandong Rd., Pingzhen Dist., Taoyuan City, Taiwan (R.O.C.)

1. Manufacture of Wireless sleep monitoring system for sleep management, Electroencephalography Amplifier and diagnostic ultrasound system.
2. Manufacture of Goniometer for the reference of rehabilitation, Ventilator, Radiofrequency Ablation Generator and Electrode Kit (Sterile Monopolar Electrode and Non-Sterile Neutral Electrode).
3. Manufacture of Medical image management and processing software.
4. Manufacture of Hearing aid.



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