

# CE Technical Documentation Review Statement

Statement Number:  
2016-TWN-MDD-0001

Place and Date:  
Taipei, 2016.01.07

## **Sigma-Care Development Co., Ltd.**

### **Site Address:**

- No. 64-3, Liau Ding Tsuen, MigSiung, Chia Yi, Taiwan, R.O.C.
- No. 35, Chung Chen Rd., Ming Siung Industrial District, Chia Yi, Taiwan, R.O.C.

### **Product Name:**

Hospital and Home Care Beds

### **Applicable EU Directive :**

Medical Device Directive 93/42/EEC as Amended

### **Product Classification:**

Class I (non-sterile, non-measuring function)

### **Project Number:**

PRJC-249685-2010-PRC-TWN

### **Review result:**

The manufacturer's technical documentation as required for class I devices, has been reviewed and found to comply with the requirements in Annex VII, section 3.

The confirmation is validated until 2021-01-07. Any change of the technical documentation should be reported to the representative office of DNV GL Business Assurance Co., Ltd. in order to examine whether the statement remains valid.

DNV GL –Business Assurance



David Hsieh  
**District Manager,**  
Taipei, 07 January 2016

The technical documentation examination is based on the stated data made available to DNVGL and the firm's documentation is presented to meet the essential requirement. The class I product is with the self-declaration for the labelling CE mark. The statement is not a mandatory for the regulatory requirement.

DNVGL TAIWAN 29Fl, No. 293, Sec.2 Wenhua Rd., Banqiao District, new Taipei City 220, Taiwan. Tel.: +886-2-82537800. [www.dnvgl.com.tw](http://www.dnvgl.com.tw)

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## Appendix to Statement

Appendix to Statement no. : 2016-TWN-MDD-0001  
Manufacturer : Sigma-Care Development Co., Ltd.  
Product group : Hospital and Home Care Beds

Statement history:

| Revision | Description                    | Issue Date |
|----------|--------------------------------|------------|
|          | Original Statement – new issue | 2016-01-07 |

The Statement referred to above covers the following products:

### Product Type(s)/Model(s):

B series, BH series, BP series, ST series, BT series, ET series, CA series, MF series, SE series

### Sites Covered by this statement :

| Site Name   | Address   |
|---|---|
| Sigma-Care Development Co., Ltd.<br>-head office, factory | No. 64-3, Liao Ding Tsuen, Ming Siung, Chia Yi, Taiwan, R.O.C.                  |
| Sigma-Care Development Co., Ltd.<br>-legal manufacturer   | No. 35, Chung Chen Rd., Ming Siung Industrial District, Chia Yi, Taiwan, R.O.C. |

### EU Representative:

| Name                            | Address  |
|---------------------------------|--|
| Specialist Mattress System Ltd. | Unit 4 Evans Business Centre, North Road, Ellesmere Port Wirral Ch65 IAE, UK |

### Refer to Technical Construction File:

TCF of Sigma-Care Development Co., Ltd.  
Revision 2, dated 2015/11/02

DNV GL –Business Assurance



David Hsieh  
**District Manager,**  
Taipei, 07 January 2016