



EC DECLARATION OF CONFORMITY

Attn: To whom it May concern

We, the manufacturer, responsible for making this declaration :

SIGMA CARE Development Co., Ltd.

No. 5, Dapumeiyuanqu 20th Rd., Dalin Township, Chiayi County 622, Taiwan (R.O.C)

For the following equipment as mentioned in CE certificate attached

Which is originally issued by DNV GL Norway:

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning Medical Devices Directive (93/42/EEC)

For the evaluation regarding the **Class I** product safety aspects, the following standards were applied :

ISO13485:2003, ISO14971:2007, EN 980 : 2008, EN 60601-1-1: 2000, EN 60601-1-2 : 2005



Product Type(S)/Model(s):

Please see product list as attachment

Nguyễn Quang Anh

北經專區
Case No. **201914** 日期: **OCT - 9 2019**
Date
本文件之簽名或蓋章，在台灣台北地方法院所屬民間公證人楊昭國盧榮輝聯合事務所認證。公證人楊昭國
Attested at the Yang, Jau-Gwo & Lu, Rong-Huei Notary Public
Office of Taiwan Taipei District Court, R.O.C., that the
signature(s)/seal (s) in this document is/are
authentic.
Notary Public *[Signature]*
Yang, Jau-Gwo

2/F, 58 FuXing N. Rd., Taipei, Taiwan, R.O.C.

[Handwritten Signature]



2019/10/03

Overseas Manager
(Position/Title)

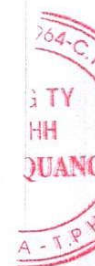
(Legal Signature)

(Date)

SIGMA CARE

	BB-100S	Bassinets	
	BB-100M	Bassinets	
Psychosis Bed Series	SB-901	Psychosis Bed	
Shower Bed Series	ST-1000	Shower Bed	
	ST-6000	Shower Bed	
Emergency Stretcher Series	BT-100	Emergency Stretcher	1 crank
	BT-200	Emergency Stretcher	2 cranks
	BT-300	Emergency Stretcher	3 cranks
	BT-600	Emergency Stretcher	1 crank
	BT-600S	Emergency Stretcher	1 crank
	BT-500	Emergency Stretcher	1 crank
	BT-800	Emergency Stretcher	1 crank
Foam Mattress Series	MC-1000	Mattress Cover	
	MF-100	Mattress	
	MF-101	Mattress	
	MF-102	Mattress	
	MF-103	Mattress	
	MF-104	Mattress	
	MF-105	Mattress	
Air Mattress Series	MA-2000	Air Mattress	
	MA-4000	Air Mattress	
	MA-5000	Air Mattress	
	MA-5800	Air Mattress	
	MA-8000	Air Mattress	
Examination Table Series	ET-101	Examination Table	
	ET-102	Examination Table	
	ET-103	Examination Table	1 motor
Bedside Cabinet Series	CA-001	Bedside Cabinet	
	CA-002	Bedside Cabinet	

Version : 2019/06/25





	SE-018	Footstool	
	SE-019	Work Chair	
	SE-020	Ward Screen	
	SE-021	Overbed Table	
	SE-022	Dress Cart	
	SE-023	Dress Cart with Lid	
	SE-024	Overbed Table	
	SE-024T	Overbed Table	
	SE-025L	Deluxe Overbed Table	
	SE-026	Stainless I.V. Stand with Caster	

