



# DET NORSKE VERITAS

## CERTIFICATE OF CONFORMITY

Application of Council Directive 93/42/EEC of 14 June 1993.

**Certificate no.: 2006-RGC-MDD-0005**

This is to certify that the technical documentation for the product:

### **Non-Sterile, Non-Invasive & Non-Active Medical Device**

*Manufactured by*

**Sigma Medical Supplies Corp.**

*at*

No. 34 & 96, Ding-Ping Rd. Rwei Fang Industrial Park, Rwei Fang Dist. New Taipei City, Taiwan, R.O.C. /  
#2 Factory, Wangshan Science & Technology Innovation Park, 33 Mulin Rd., Yuexi, Suzhou, China 215104

**complies with the requirements applicable to it**

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.

Further identification and description of the products covered by this certificate are given in the Appendix.

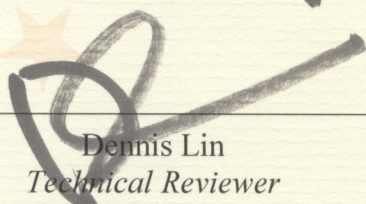
*Taipei: 10 August 2011*

Valid until: 10 August 2016

for Det Norske Veritas  
Region Greater China

#### **Limitations:**

Any changes of the medical devices shall immediately be reported to Det Norske Veritas Region Greater China in order to examine whether this Certificate remains valid.

  
Dennis Lin  
Technical Reviewer  
DNV R.G.C. Product Certification

*Any significant changes in design or construction of the product, or amendments to the Directive or Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.*

**CERTIFICATE OF CONFORMITY**

**APPENDIX**

Appendix to Certificate no. : 2006-RGC-MDD-0005  
Manufacturer : Sigma Medical Supplies Corp.  
Product group : Non-Sterile, Non-Invasive & Non-Active Medical Device

**Certificate history:**

Revision	Description	Issue Date
	<b>Original certificate</b>	<b>2006-8-21</b>
<b>0</b>	<b>Re Certification plus product scope extension</b>	<b>2011-8-10</b>

The Certificate referred to above covers the following products:

Rolls and Pouches for Medical Use & Sterilization Indicator Tapes:

- SMFR-001 ~ SMFR-999
- SMGR-001 ~ SMGR-999
- TYFR-001 ~ TYFR-999
- SMSE050000 ~ SMSE050999
- SMFP050000 ~ SMFP050999
- SMGP050000 ~ SMGP050999
- IT-0000S ~ IT-9999S
- IT-0000E ~ IT-9999E
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Feeding Bag Tube Guide :

- SMPS 0001-0999

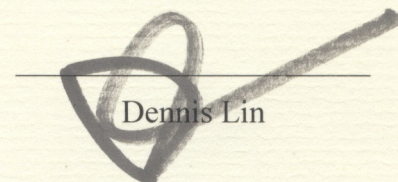
Refer to Technical Construction File:

Rolls and Pouches for Medical Use & Sterilization Indicator Tapes: Document No.: 06-101

Feeding Bag Tube Guide :Document No.: SM-R-014

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10 August 2011



Dennis Lin