



SRITONG GROUP

## HEALTHY GLOVE CO., LTD

169 Moo 4, T.Lam Thap, A. Lam Thap, Krabi 81120 Tel: 081-9597933 Fax : 074-245061  
169 หมู่ที่ 4 ตำบลลำทับ อำเภอลำทับ จังหวัดกระบี่ 81120 โทร. 081-9597933 โทรสาร 074-245061

### EC DECLARATION OF CONFORMITY

Plant of Manufacture : 119 Kanchanavanich Road, Tambol Patong, Hatyai,  
Songkhla 90230, Thailand

Product : Power Free Nitrile Rubber Examination Gloves.

Intended Use : For the covering of hands of medical staff during  
examination procedures involving patient body surfaces  
and patient body orifices.

The undersigned hereby declares, on behalf of **Healthy Glove Co., Ltd**, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of Medical devices directive 93/42/EEC.

**Healthy Glove Co., Ltd's** quality management system has been certified by TÜV Süd for the manufacture of natural and synthetic latex examination gloves, and in compliance with the requirements of ISO 9001:2008 and ISO 13485:2003.

All supporting documentation is retained under the premises of the manufacturers.

#### Reference Standards :

En 455-1 : Medical gloves for single use - part 1  
Requirements and testing for freedom from holes.

EN 455-2 : Medical gloves for single use - part 2  
Requirements and testing for physical properties.

EN 455-3 : Medical gloves for single use - part 3  
Requirements and testing for Biological Evaluation

EN455-4 : Medical gloves for single use - part 4  
Requirements and testing for shelf life determination.

Signed / Stamped by

Name : Teoh Choh Shee

Position : Managing Director

Date : 6/5/15