HAW PAR HEALTHCARE LIMITED
2 Chia Ping Road #09-03 Haw Par Tiger Balm Building Singapore 619968
Tel: (65) 6303 7333 Fax: (65) 6264 3211
Mailing Address:
401 Commonwealth Drive #03-03 Haw Par Technocentre Singapore 149598
Website: www.tigerbalm.com *Company Registration No: 198801793M*
A MEMBER OF THE 虎豹 Haw Par GROUP

EC DECLARATION OF CONFORMITY

Tiger Balm Plaster, Medical Device Class 1, is manufactured by Haw Par Healthcare Limited in compliance with the European Community Medical Device Annex VII of Directive 93/42/EEC. Assessment of compliance of the product with the requirements relating to the Medical Device was based on standard:

1. EN 1041:2008 Information supplied by the manufacturer of medical devices
2. ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
3. ISO 14971:2012 Medical devices. Application of risk management to medical devices
4. ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
5. EN ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
6. IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices
7. IEC 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices

The medical device is produced by our manufacturing site located at No. 2 Chia Ping Road, Haw Par Tiger Balm Building, Singapore 619968.

Attachments:

1. GMP Certificate, Certificate No.: MCGM1700047
2. ISO Certificate 9001:2008, Certificate No.: 2004-1-0716
3. In-house Product Specification
4. Typical Certificate of Analysis

I hereby declare that, having read and understood the Essential Requirements of the Council Directive 93/42/EEC and the information furnished are true and accurate.

Name : Kow Mui Lick

Signatory : [signature]

Date : 2017.03.31

Position : Senior Manager (Quality & Regulatory Affairs)

CERT NO.: 2004-1-0716
ISO 9001 : 2008