



**WeTAPE Inc.**

269-9, Yangjae-dong, Seocho-gu, Seoul, 137-895, Korea  
Tel: 82-1544-3261 Fax: 82-2-2057-8860  
www.rocktape.com / cullen@rocktape.com

## **EC Declaration of Conformity**

**Manufacturer : WeTAPE Inc.**  
269-9, Yangjae-dong, Seocho-gu, Seoul, 137-895, Korea

**European representative : ROCKTAPE GERMANY GmbH**  
Völckersstraße 7, 22765 Hamburg, Germany

**Product : Rocktape (Medical Tape Adhesive)**

**Classification : Class I by Rule 1 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC**

**Conformity Assessment Route : Annex VII, MDD 93/42/EEC as amended by 2007/47/EC**

**We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.**

**Standards Applied**

- Council Directive 93/42/EEC as amended by 2007/47/EC of 5 September 2007 concerning medical devices
- ISO 13485 [2003] Medical devices – Quality management system – Requirements for regulatory purposes
- ISO 14971 [2007] Medical devices-Application of risk management to medical devices

**Start of CE-marking : 2012.10. 1**

**Place, Date of issue : Seoul Korea, 2012. 10. 1**

**Signature:**



**WeTAPE Inc.**  
269-9 Yangjae-dong  
Seocho-gu, Seoul 137-895  
Korea  
T 82-1544-3261 F 82-31-975-7555



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**President on behalf of WeTAPE Inc..**