

# CERTIFICATE

Number: 2036399CE01



## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Bfactory Health Products B.V.**  
Remmerden 58  
3911 TZ Rhenen  
The Netherlands

For the product category:

**Honey based devices used for wound care and vaginal application**

KEMA Quality grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

**0344**

Documents, that form the basis of this certificate:

**Certification Notice 2036399CN, initially dated December 11, 2003**  
**Addendum, initially dated December 11, 2003**

KEMA Quality hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: January 15, 2011  
Issued for the first time: December 11, 2003  
Reissued: January 15, 2010

KEMA Quality B.V.

drs. G.J. Zoetbrood  
Managing Director

M. McCann  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2036399CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Honey based devices used for wound care and vaginal application

Issued to:

### **Bfactory Health Products B.V.**

**Remmerden 58  
3911 TZ Rhenen  
The Netherlands**

This certificate covers the following product(s):

Honey based devices used for wound care

Revamil pure, single dose  
Dermasilk  
Nasumel  
DerMel  
Revamil Wound Dressing  
DerMel wondverband  
Revamil Balm  
AnaMel  
DermagiQ)

Honey based devices for vaginal microfloral disbalance

Products: Revamil FEM

Initial date: December 11, 2003

Revision date: April 9, 2010

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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