

# CERTIFICATE

Number: 2119704CE01



## CE MARKING OF CONFORMITY MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

Issued to:

**TAUREON**Laan van Zuid Hoorn 61  
2289 DC Rijswijk Zh  
The Netherlands

For the product category:

**Wound care products and resorbable collagen material for haemostasis**

KEMA 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**

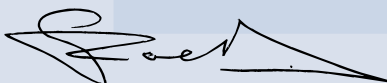
Documents, that form the basis of this certificate:

**Certification Notice 2119704CN, initially dated October 20, 2008**  
**Addendum, initially dated October 20, 2008**

KEMA 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 III and VII for Class IIa, IIb and III products is executed by the Manufacturer in accordance with the provisions of the **Council Directive 93/42/EEC of June 14, 1993**. Additionally for the class III device specified on the addendum, KEMA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of the **Directive 2003/32/EC of April 23, 2003** concerning medical devices manufactured utilising tissue of animal origin.. 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: August 1, 2012  
Issued for the first time: October 20, 2008  
Reissued: July 28, 2009

KEMA Quality B.V.

drs. G.J. Zoetbrood  
Managing DirectorM. McCann  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2119704CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

**Wound care products and resorbable collagen material for haemostasis**

Issued to:

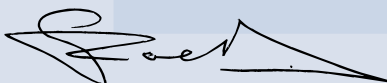
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The Netherlands

This certificate covers the following product(s):

SurfaSoft (Class IIa)  
HoneySoft (Class IIb)  
Novacol Resorbable Collagen Fibrillar and Pad material for Haemostasis (Class III)

Initial date: October 20, 2008

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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### KEMA Medical

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