

# CERTIFICATE

Number: 65263CE02

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Humeca B.V.**  
Het Bijvank 251-a  
7544 DB Enschede  
The Netherlands

For the product category:

### **Dermatome and Dermatome Blade**

DEKRA 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 65263CN, initially dated 1 January 1998**  
**Addendum, initially dated 14 April 2004**

DEKRA 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: 1 July 2014  
Issued for the first time: 14 April 2004  
Reissued: 1 July 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

# ADDENDUM

Belonging to certificate: 65263CE02

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Dermatome and Dermatome Blade

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**The Netherlands**

This certificate covers the following product(s):

Dermatome, electrically powered

Dermatome Blade, single use

Sober Dermatome Blade, single use

Padget Dermatome Blade, single use

Initial date: 14 April 2004

Revision date: 27 June 2008

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

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