

# CERTIFICATE

Number: 2126845CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Bactiguard AB**

Biblioteksgatan 25

PO Box 5070

102 42 Stockholm

Sweden

For the product category:

**Urinary catheters with Bactiguard® coating**  
**Endotracheal Tube with Bactiguard® coating**

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 2126845CN, initially dated 9 November 2009**  
**Addendum, initially dated 23 October 2009**

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 II for class IIa and IIb products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II section 4 is mandatory. 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: 23 October 2012

Issued for the first time: 23 October 2009

Revised: 15 March 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: 2126845CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Urinary catheters with Bactiguard<sup>®</sup> coating  
Endotracheal Tube with Bactiguard<sup>®</sup> coating

Issued to:

### **Bactiguard AB**

**Biblioteksgatan 25  
PO Box 5070  
102 42 Stockholm  
Sweden**

This certificate covers the following product(s):

BIP Foley Catheter Silicone (Class IIb)  
BIP Foley Catheter (Class IIb)  
BIP Endotracheal tube (Class IIa)

Initial date: 23 October 2009  
Revision date: 15 March 2011

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing A.A.M. Laan.

ing A.A.M. Laan  
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