

CERTIFICATE

Number: 2126845CE01



CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Bactiguard ABBiblioteksgatan 25
114 35 Stockholm
Sweden

For the product category:

Urinary catheters with Bactiguard coating

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

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 II 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: March 21, 2010
Issued for the first time: October 23, 2009

KEMA Quality B.V.

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

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KEMA MedicalKEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 26 356 2000 F +31 26 352 5800 www.kemaquality.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2126845CE01

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CE MARKING OF CONFORMITY MEDICAL DEVICES

Urinary catheters with Bactiguard coating

Issued to:

Bactiguard AB
Biblioteksgatan 25
114 35 Stockholm
Sweden


This certificate covers the following product(s):

BIP Foley Catheter Silicone
BIP Foley Catheter

Initial date: October 23, 2009

Revision date: December 21, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

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KEMA Medical

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