

CERTIFICATE

Number: 2001438TE01



EC TYPE-EXAMINATION MEDICAL DEVICES

Issued to:

CD Leycom
Argonstraat 116
2718 SP ZOETERMEER
THE NETHERLANDS

For the product category:

Pressure, Volume and Pressure / Volume Catheter

Documents, that form the basis of this certificate:

Certification Notice 2036193CN, initially dated January 1, 2006

KEMA hereby certifies 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 the type of the products falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of June 14, 1993, in accordance with Annex III of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: January 1, 2012
Issued for the first time: October 1, 2000
Reissued: January 7, 2009

drs. G.J. Zoetbrood
Managing Director

dr. ir. G.W. Bos
Certification Manager

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KEMA Medical

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