

CERTIFICATE

Number: 3900167CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Caesarea Medical Electronics GmbH

23 Staufenburg st.
72805 Lichtenstein
Germany

For the product category:

Infusion Pumps and Enteral Feeding pumps

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 3900167CN, initially dated 13 July 2010
Addendum, initially dated 13 July 2010

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 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: 1 June 2015
Issued for the first time: 13 July 2010
Reissued: 26 June 2012

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 3900167CE01

1/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Infusion Pumps and Enteral Feeding pumps

Issued to:

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This certificate covers the following product(s):

Enteral Feeding pumps (class IIb)
- model NOA III

Ambulatory Infusion Pump, (class IIb)
- model BodyGuard 323
- model BodyGuard 575
- model BodyGuard 545
- model BodyGuard 595
- model BodyGuard 323 Vision
- model BodyGuard 323 Color Vision
- model BodyGuard 545 Color Vision
- model BodyGuard 575 Color Vision
- CMExpress
- Applicra 2002

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A blue ink signature of G.J. Zoetbrood.

drs. G.J. Zoetbrood
Managing Director

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

ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 3900167CE01

2/2

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Infusion Pumps and Enteral Feeding pumps

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Ambulatory Syringe Pump, (class IIb)

- model Niki T34
- model T34L
- T34L PCA
- CME-PM
- Neofeed

Ambulatory Dual channel Infusion Pump, (class IIb)

- model BodyGuard 121 Twins

Ambulatory Multi Channel Infusion Pump, (class IIb):

- model BodyGuard Quadro

Initial date: 13 July 2010

Revision date: 19 July 2013

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drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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