

CERTIFICATE

Number: 59802CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Nutricia Medical Devices B.V.

Schiphol Boulevard 261
1118 BH Schiphol Airport
The Netherlands

For the product category:

Flocare® Enteral feeding systems / tubes

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 93928CN, initially dated 1 July 1999
Addendum, initially dated 1 April 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 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 September 2013
Issued for the first time: 5 December 1995
Reissued: 1 September 2010

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.

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ADDENDUM

Belonging to certificate: 59802CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Flocare® Enteral feeding systems / tubes

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The Netherlands

This certificate covers the following product(s):

Flocare® Pack feeding sets

Flocare® Top Fill reservoir sets

Flocare® MC Pack feeding sets

Flocare® Universal feeding sets

Flocare® Universal Pack feeding sets

Flocare® NG tubes PVC

Flocare® Spike feeding sets

Initial date: 1 April 2010

Revision date: 8 August 2012

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, consisting of a stylized 'Z' followed by 'oetbrood'.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of A.A.M. Laan, consisting of a stylized 'L' followed by 'aan'.

ing. A.A.M. Laan
Certification Manager

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