EC CERTIFICATE

Number: 93928CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Nutricia Medical Devices B.V.

Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

For the product category(ies)

Enteral Feeding Systems and Long term Use Catheters for the administration of enteral feeding, including associated accessories

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 23 March 2016

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities 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 2022
Issued for the first time: 23 March 2016
Reissued: 12 September 2017
Revised: 2 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 93928CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Enteral Feeding Systems and Long term Use Catheters for the administration of enteral feeding, including associated accessories

Issued to:

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

This certificate covers the following product(s):

Enteral feeding sets :
- Flocare® Pack feeding sets
- Flocare® Top Fill reservoir sets
- Flocare® Pack & Bottle feeding sets
- Flocare® Bottle feeding sets

Sterile Accessories for Flocare® enteral feeding systems:
- Flocare® Bolus Set
- Flocare® Reservoirs
- Flocare® Containers
- Flocare® Caps and Adapters
- Flocare® Feeding connectors
- Flocare® Extension sets
- Flocare® Guide wires
- Flocare® External retention devices

Long term use catheters for administration of enteral feeding
Naso-gastric/intestinal Feeding tubes for long term use:
- Flocare® PUR (various sizes/configurations)
- Flocare® PUR Soft (various sizes/configurations)
- Flocare® Nutrisoft (various sizes/configurations)

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: 93928CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Enteral Feeding Systems and Long term Use Catheters for the administration of enteral feeding, including associated accessories

Issued to:

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp
The Netherlands

- Flocare® Bengmark Nasointestinal (NI) feeding tube (various sizes)
- Flocare® Bengmark Duo-Tube
- Flocare® Bengmark PEG/J feeding tube

Enterostomy Feeding tubes for long term use
Percutaneous Endoscopic Gastrostomy sets):
- Flocare® P.E.G. sets (various sizes)

Gastrostomy tubes, Balloon catheters (G-tubes):
- Flocare® Gastrostomy tubes (G-tubes) (various sizes)

Initial date: 23 March 2016
Revision date: 2 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396