

EC CERTIFICATE

Number: 93928CE01

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)

Flocare® Infinity™ Enteral feeding pumps and 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 2 December 2002

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: 26 May 2024
Issued for the first time: 1 July 1999
Reissued: 25 May 2021
Revised: 2 July 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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

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ADDENDUM

Belonging to certificate: 93928CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Flocare® Infinity™ Enteral feeding pumps and accessories

Issued to:

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

This certificate covers the following product(s):

Flocare® Infinity™ Enteral feeding pumps accessories:

- Flocare® Infinity™ Nurse Call
- Flocare® Infinity™ Data Cable

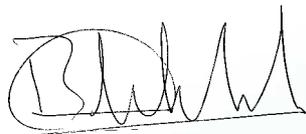
Flocare® Infinity™ enteral feeding pumps

- Flocare® Infinity™ +
- Flocare® Infinity™ II
- Flocare® Infinity™ France
- Flocare® Infinity™ III

Initial date: 2 December 2002

Revision date: 2 July 2019

DEKRA Certification B.V.

A handwritten signature in black ink, appearing to read "B.T.M. Holtus".

B.T.M. Holtus
Managing Director

A handwritten signature in black ink, appearing to read "J.A. van Vugt".

J.A. van Vugt
Certification Manager

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