

Number: 2262711CE01

# EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

**Nutricia Medical Devices B.V.**

Taurusavenue 167

2132 LS Hoofddorp

The Netherlands

SRN ID.: NL-MF-000012729

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 EU- Regulation which apply to them:

## 0344

**Supplement to certificate: 93928CN**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Principal Certification Manager

First Issued: 27 July 2022

Date: 27 July 2022

Expiry date: **27 July 2027**

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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 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

NBOG MDN 1202:

Non-active non-implantable devices for administration, channeling and removal of substances, including devices for dialysis (class Is)

Sterilization method: Ethylene oxide

Flocare Gravity Giving Sets:

- Flocare Gravity Pack Set
- Flocare Gravity Pack & Bottle Set
- Flocare Gravity TF Res. Set 2.0 L
- Flocare Gravity Set TF Res. Set 1.3 L
- Flocare Gravity Bottle Set

Flocare Accessories:

- Flocare Bolus Set
- Flocare Button Extension Set Plus
- Flocare Extension Set – 100 cm
- Flocare Button Extension Set
- Flocare TF Res. Pack Conn. 2.0 L – Cross
- Flocare TF Res. Pack Conn. 1.3 L – Cross
- Flocare Conn Two Pack – Cross Spike
- Flocare ENFIT Swivel Adapter

NBOG MDN 1202:

Non-active non-implantable devices for administration, channeling and removal of substances, including devices for dialysis (class IIa)

Flocare Infinity Giving Sets:

- Flocare Infinity Pack Set w/o DC Y-Port
- Flocare Infinity Pack Set w/o DC & w/o MP
- Flocare Infinity Pack Set w/o DC
- Flocare Infinity Pack Set
- Flocare Infinity Pack TwinLine Set

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# EU Quality Management System Certificate

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- Flocare Infinity Pack Mobile Set
- Flocare Infinity Pack Mobile Set w/o MP
- Flocare Infinity Pack Mobile Set Y-Port
- Flocare Infinity Pack & Botte Mobile Set
- Flocare Infinity Pack & Bottle Set
- Flocare Infinity Bottle Set
- Flocare Infinity Bottle Set w/o MP
- Flocare Infinity Bottle Set Y-Port
- Flocare Infinity TF Res. Set 1.3
- Flocare Infinity TF Res. Set 2.0

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Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

## Certificate History

*Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.*

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	27 July 2022	93928CN44	First issue 2262711CE01
1			
2			

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