Number: 2262711CE02

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.M.A. McKenzie
Principal Certification Manager

First Issued: 2 November 2022

Date: 2 November 2022

Expiry date: 1 November 2027

 $\ensuremath{\mathbb{C}}$ Integral publication of this certificate and adjoining reports is allowed

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

Number: 2262711CE02

EU Quality Management System Certificate

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

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

G02020101, Nasogastric tubes (Class IIb)			
Flocare PUR nasogastric feeding tubes	1.4. 1.18		
Flocare PURSoft nasogastric feeding tubes	Intended Purpose: Flocare nasogastric feeding tubes are intended for nutrition administration of enteral feeding into the		
Flocare Nutrisoft nasogastric feeding tubes	stomach		
G02020102, Nasojejunal/nasoduodenal tubes (Class lib)			
Flocare Bengmark nasointestinal feeding tubes			
	/Intended/Purpose:////////////////////////////////////		
	Flocare nasointestinal feeding tubes are intended		
	for nutrition administration of enteral feeding into		
	the intestine		

First Issued: 2 November 2022 Date: 2 November 2022 © Integral publication of this certificate and adjoining reports is allowed

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Conditions for or limitations to the validity of this certificate:

N/A

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	2 November 2022	93928CN46	First issue 2262711CE02
1		<i></i>	///X///////////////////////////////////
2	//		////

First Issued: 2 November 2022 Date: 2 November 2022 Expiry date: 1 November 2027 © Integral publication of this certificate and adjoining reports is allowed

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