Number: 2262711CE03

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: 22 September 2022 Date: 22 September 2022 Expiry date**: 22 September 2027**

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: 2262711CE03

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):

N-BOG MDN 1202 Non-active non-implantable devices for administration, channeling and removal of substances, including devices for dialysis **Sterilization method: EtO**
Flocare Containers (0.5L & 1.0L)

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	22 September 2022	93928CN45	First issue 2262711CE03
1			
2			

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