DECLARATION OF CONFORMITY (medical devices)

DoC NMD 93928CE02_010 Flocare PEG set_REG (EU) 2023607 amendment

This DoC is updated and re-issued again following the publication of the REG (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Nutricia Medical Devices B.V., having its registered office at Taurusavenue 167 / 2132 LS Hoofddorp (The Netherlands), hereinafter referred to as: “Nutricia”, hereby declares that the distributed CE marked products, specified in the annexed product list, are class IIb devices and conform to the type(s) covered by the EC Certificate, reference number: 93928CE02, issued for the first time on 23 March 2016 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and fulfils the relevant provisions of the “Besluit Medische Hulpmiddelen”, the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices, including all subsequent amendments.

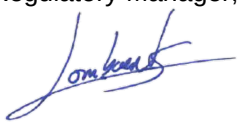
This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:2016 (+A11:2021), Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344.

This Declaration of Conformity covers the Flocare® products as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following production site:

- Nutricia Pharmaceutical Wuxi Co. Ltd. No. 17 XinMing Road, Wuxi, High-tech Development Zone, Jiangsu Province, P.R. China 214111

Hoofddorp, 20 March 2023

Regulatory Manager, PRRC



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Mr. M.E. Lombaerts

Annexes

- Annex A Product list
- Annex B History sheet

Annex A to the Declaration of Conformity (Product list)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_010 Flocare PEG set_REG (EU) 2023607 amendment* and specifies the CE-marked products concerned that Nutricia Medical Devices B.V. intends to distribute in conformity with the provisions of the "Besluit Medische Hulpmiddelen", which is the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. The following list identifies the products by name and article-number.

Flocare® Percutaneous Endoscopic Gastrostomy sets, class IIb
(GMDN-code 64464 – gastrostomy tube kit, non-medicated)

Product Code (REF)	**SAP (logistical code)**	**Product name**	**Product Type**	**Last Product LOT** (under MDD cert)	***First LOT*** *(under REG (EU) 2023/607)*	***Last LOT*** *(under REG (EU) 2023/607)*
594820	94820	Flocare® PEG set	ENFit Ch10	101218173	*101263323*	-
594821	94821	Flocare® PEG set	ENFit Ch14	101217840	*101263316*	-
594822	94822	Flocare® PEG set	ENFit Ch18	101208966	*101263319*	-

(**Flocare® Enteral feeding tubes for long term use, class IIb**)
(GMDN-code 35419 Gastrostomy tube)

Product Code (REF)	**SAP (logistical code)**	**Product name**	**Product Type**	**Last Product LOT** (under MDD cert)	***First LOT*** *(under REG (EU) 2023/607)*	***Last LOT*** *(under REG (EU) 2023/607)*
594823	94823	Flocare® Bengmark PEG/J (for use with Flocare® PEG Ch18)	ENFit Ch9-105cm	101199516	*101280611*	-

Annex B to the Declaration of Conformity (History sheet)

Flocare® Percutaneous Endoscopic Gastrostomy sets, class IIb
(GMDN-code 64464 – gastrostomy tube kit, non-medicated)

This history sheet belongs to the Declaration of Conformity identified by*: DoC NMD 93928CE02_010 Flocare PEG set_REG (EU) 2023607 amendment* and specifies the revision history of the Declaration of Conformity

Rev. 010 Inclusion of first batch information after publication of the MDR amendment 2023/607 (Art120 extension)
Rev. 009 Inclusion last MDD produced batch information (MDD certificate 93028CE02 PEG expired 1 September 2022)
Rev. 008 Inclusion ISO13485 recertification, certificate date March 3rd, 2022. Inclusion PEG/J device as this is to be used in conjunction with a PEG so the same product family (previous separate DoC NMD 93928CE02_007 Flocare Bengmark)
Rev. 007 General review; update DoC template
Rev. 006 Allocation new GMDN code from 35419 to 64464
Rev. 005 Inclusion SAP logistical codes
Rev. 004 Inclusion of last batch information – update delisted product list
Rev. 003 Update to new office address from Schiphol to Hoofddorp
Update to ISO13485:2016 and revised CE certificates (new address)
Rev. 002 Update new CE certificate re-issued 12 September 2017. Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.
Rev. 001 Transfer to Annex II certification (ICC2016-009). Replacing DoC "Decl conf NMD 66211TE02_014 Flocare PEG set"
Inclusion first batch information