Nutricia Medical Devices BV

DECLARATION OF CONFORMITY (medical devices)

DoC NMD 93928CE02_006 Flocare Bengmark

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, conform to the type(s) covered by the EC Certificate, reference number: 93928CE02, issued for the first time on 23March 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.

Nutricia has implemented a quality assurance system for design, manufacture and final inspection in accordance to the provisions of Annex II of Council Directive 93/42/EC of June 14, 1993 and is subject to periodical surveillance.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, meet 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, which apply to them.

This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:2016, 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 sites:

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

Hoofddorp, 26 June 2021

RA Manager

Digitally signed by ME Lombaerts
Date: 2021.06.18 16:17:08 +02'00'

Mr. M.E. Lombaerts

Annexes

- Annex A Product list
- Annex B History sheet
- Annex C Discontinued product list

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Annex A to the Declaration of Conformity (Product list)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare Bengmark* 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® Bengmark Naso intestinal feeding tubes, class IIb**)
(GMDN-code 16798 / Nasoenteral tube)

Product Code (REF)	***SAP (logistical code)***	**Product name**	**Product Type**	**First Product LOT**	**Production Site**
594824	*94824*	Flocare® Bengmark® NI tube Ch8-145	ENFit Ch8-145cm	201510K59	NP Wuxi
594825	*94825*	Flocare® Bengmark® NI tube Ch10-145	ENFit Ch10-145cm	201510K69	NP Wuxi

(**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**	**First Product LOT**	**Production Site**
594823	*94823*	Flocare® Bengmark PEG/J (for use with Flocare® PEG Ch18)	ENFit Ch9-105cm	201510L29	NP Wuxi

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Annex B to the Declaration of Conformity (History sheet)

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare Bengmark* and specifies the revision history of the Declaration of Conformity, including revisions of the respective Quality System and CE certificates.

EN ISO 13485:2003, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, revised on 15 December 2011 (multi-site structure), re-issued as EN ISO 13485:2012 on 1 September 2013, re-issued on September 30, 2016. Revised on 2 July 2019 for ISO13485:2016 transition with the new Hoofddorp address.

CE Marking of Conformity Certificate, reference number: 66211CE01**,** issued for the first time on April 1, 1997, re-issued December 1, 2004, revised on February 26, 2007, re-issued on November 15, 2007, re-issued on September 1, 2010, re-issued on 1 September 2013, revised as certificate number 93928CE01 on 23 March 2016 (certificate 66211TE06 became obsolete), re-issued on September 12, 2017. Revised on 2 July 2019 for the new Hoofddorp address.

Rev. 006 Correction GMDN code PEG/J from 47656 to 35419
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 66211TE06_016 Flocare Bengmark”
Inclusion first batch information

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Annex C to the Declaration of Conformity (Discontinued Product list)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_005 Flocare Bengmark* and specifies the discontinued products within the identified certificate. Product ranges are identified by first and last produced Batch/ LOT numbers. Products will be removed from the discontinued product list after 1 year of expiry of last produced batch.

(Flocare® Bengmark Naso intestinal feeding tubes, class IIb)
(GMDN-code 16798 / Nasoenteral tube)

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production Site
35252	Flocare® Bengmark DUO-Tube double lumen tube	DUO-tube	*n/a*	never made	NP Wuxi
35230	*Flocare® Bengmark Naso-Intestinal Tube*	*Ch8-145cm*	*200812K19*	*201208N49*	*NP Wuxi*
35231	*Flocare® Bengmark Naso-Intestinal Tube*	*Ch10-145cm*	*200812K29*	*201508K09*	*NP Wuxi*
35267	*Flocare® Bengmark Naso-Intestinal Tube (with male Luer guide wire handle)*	*Ch8-145cm*	*200905L19*	*201601M09*	*NP Wuxi*
35268	*Flocare® Bengmark Naso-Intestinal Tube (with male Luer guide wire handle)*	*Ch10-145cm*	*200902L99*	*201601N39*	*NP Wuxi*
569942	*Flocare® Bengmark Naso-Intestinal Tube – ENLock*	*Ch10-145cm*	*201210K49*	*201510P19*	*NP Wuxi*
569946	*Flocare® Bengmark Naso-Intestinal Tube – ENLock*	*Ch8-145cm*	*201210K59*	*201509L09*	*NP Wuxi*
570119	*Flocare® Bengmark DUO-Tube Ch18-9 - ENLock*	*Ch18-9*	*201212M49*	*201305L89*	*NP Wuxi*

(Flocare® Enteral feeding tubes for long term use, class IIb)
(GMDN-code 47656 / Gastrojejunostomy tube)

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production Site
35430	Flocare® Bengmark PEG/J for use with Flocare® PEG Ch18	Ch9-105 cm	201103L49	201209K89	NP Wuxi
570118	*Flocare® Bengmark PEG/J Ch9 - ENLock*	*Ch9-105cm*	*201210N39*	*201510P29*	*NP Wuxi*