Nutricia Medical Devices BV

DECLARATION OF CONFORMITY (medical devices)

DoC NMD 93928CE02_006 Flocare PEG set

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 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.

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 site:

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

Hoofddorp, 29 June 2021

RA Manager

Digitally signed by ME Lombaerts
Date: 2021.06.29 16:08:00 +02'00'

Mr. M.E. Lombaerts

Annexes

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

Nutricia Medical Devices BV

Annex A to the Declaration of Conformity (Product list)

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

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare PEG set* 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.

Product Code (REF)	***SAP (logistical code)***	**Product name**	**Product Type**	**First Product LOT**	**Production Site**
594820	*94820*	Flocare® PEG set	ENFit Ch10	201602M89	NP Wuxi
594821	*94821*	Flocare® PEG set	ENFit Ch14	201601M59	NP Wuxi
594822	*94822*	Flocare® PEG set	ENFit Ch18	201601L59	NP Wuxi

Nutricia Medical Devices BV

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_006 Flocare PEG set* 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 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. Revised on 2 July 2019 for the new Hoofddorp address.

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

Nutricia Medical Devices BV

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

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

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare PEG set* 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.

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production Site
35448	Flocare® PEG-set (with MLL XTREE connector)	Ch14	201111K39	201208L19	NP Wuxi
35449	Flocare® PEG-set (with MLL XTREE connector)	Ch18	201108N59	201206K39	NP Wuxi
35483	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH14	n/a never produced		NP Wuxi
35484	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH18	201211N99	201306K49	NP Wuxi
35427	*Flocare® PEG-set*	*Ch10*	*n/a – never made*	*n/a*	*NP Wuxi*
35428	*Flocare® PEG-set*	*Ch14*	*201109K39*	*201207M29*	*NP Wuxi*
35429	*Flocare® PEG-set*	*Ch18*	*201105K39*	*201511P19*	*NP Wuxi*
569866	*Flocare® PEG-set – ENLock (for enteral feeding)*	*Ch18*	*201211L19*	*201511L09*	*NP Wuxi*
569869	*Flocare® PEG-set – ENLock (for enteral feeding)*	*Ch10*	*201210K19*	*201510L89*	*NP Wuxi*
569870	*Flocare® PEG-set – ENLock (for enteral feeding)*	*Ch14*	*201210K29*	*201510M79*	*NP Wuxi*