

DECLARATION OF CONFORMITY (Medical devices)

DoC NMD 93928CE02_006 Flocare Gastrostomy tube

Nutricia Medical Devices B.V., having its registered office at Taurus avenue 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.

This declaration is supported by the Quality System certification based on the harmonized standard 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:

- Degania Silicone Limited. Address: *Kibbutz, Degania Bet 1513000, Israel (DSL)*
 - Assembly by Degania Medical Devices PVT LTD, India or Degania Silicone Limited, Israel
 - Sterilisation by Degania Medical Devices PVT LTD, India or Mediplast Israel LTD

Hoofddorp, 27 January 2021

RA Manager

Mr. M.E. Lombaerts

Annexes

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

Annex A to the Declaration of Conformity (Product list)

Flocare® Gastrostomy tubes, class IIb (GMDN-code 35419 / Gastrostomy tube)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare Gastrostomy tube* 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, article-number and batch/lot number.

Product Code (REF)	SAP (logistical code)	Product name	Product Type	First Product LOT	Production Site
594814	94814	Flocare® Gastrostomy tube (G-tube)	Ch10 Balloon catheter - ENFit	P1549914	Degania (Israel)
594815	94815	Flocare® Gastrostomy tube (G-tube)	Ch14 Balloon catheter - ENFit	P1549918	Degania (Israel)
594816	94816	Flocare® Gastrostomy tube (G-tube)	Ch16 Balloon catheter - ENFit	P1549922	Degania (Israel)
594817	94817	Flocare® Gastrostomy tube (G-tube)	Ch18 Balloon catheter - ENFit	P1549926	Degania (Israel)
594818	94818	Flocare® Gastrostomy tube (G-tube)	Ch20 Balloon catheter - ENFit	P1549930	Degania (Israel)

Annex B to the Declaration of Conformity (History sheet)

Flocare® Gastrostomy tubes, class IIb (GMDN-code 35419 / Gastrostomy tube)

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare Gastrostomy tube* 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 on 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 66211TE04 became obsolete), re-issued on September 12, 2017. Revised on 2 July 2019 for the new Hoofddorp address.

Rev. 006 Inclusion SAP logistical codes

Rev. 005 Update to new office address from Schiphol to Hoofddorp

Update to ISO13485:2016 and revised CE certificates (new address)

Rev. 004 Correction of addresses and production locations, inclusion last batch information of delisted devices Annex C (non ENFit)

Rev. 003 Update new CE certificate re-issued 12 September 2017. Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.

Rev. 002.1 Correction of DoC reference version in Annex B and C from v_001 to v_002

Rev. 002 Inclusion of first batch information ENFit G-tubes

Rev. 001 Transfer to Annex II certification (ICC2016-009), Replacing DoC "Decl conf NMD 66211TE04_011 Flocare Gastrostomy tube"

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

Flocare® Gastrostomy tubes, class IIb (GMDN-code 35419 / Gastrostomy tube)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_006 Flocare Gastrostomy tube* 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
3523	Flocare® Gastrostomy tube	Ch10 Balloon catheter	200010102	200702132	MRI-NHC S.A.
			200705122	091210019	MRI-IPN HC SA
3524	Flocare® Gastrostomy tube	Ch14 Balloon catheter	200011102	200612142	MRI-NHC S.A.
			200611502	200611502	Degania-IPN HC SA
3524			200703102	091211019	MRI-IPN HC SA
3525	Flocare® Gastrostomy tube	Ch18 Balloon catheter	200003102	200702102	MRI-NHC S.A.
			200703162	091212019	MRI-IPN HC SA
			200611512	200611512	Degania-IPN HC SA
35425	Flocare® Gastrostomy tube	Ch16 Balloon catheter	200003162	200701132	MRI-NHC S.A.
			200703112	091213019	MRI-IPN HC SA
35426	Flocare® Gastrostomy tube	Ch20 Balloon catheter	200007102	200702172	MRI-NHC S.A.
			200704102	091214019	MRI-IPN HC SA
35485	Flocare® Gastrostomy tube	Ch10 Balloon catheter	P1000193	S15004101 (exp 11/2020)	Degania (India)
35486	Flocare® Gastrostomy tube	Ch14 Balloon catheter	P0923946	S15003890 (exp 11/2020)	Degania (India)
35487	Flocare® Gastrostomy tube	Ch16 Balloon catheter	P0925104	S15004740 (exp 12/2020)	Degania (India)
35488	Flocare® Gastrostomy tube	Ch18 Balloon catheter	P0923947	S15005053 (exp 12/2020)	Degania (India)
35489	Flocare® Gastrostomy tube	Ch20 Balloon catheter	P0925106	S16000138 (exp 01/2021)	Degania (India)