

DECLARATION OF CONFORMITY (medical devices)

DoC NMD 93928CE02_009 Flocare NG_NI feeding tubes

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, 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® Nasogastric/*intestinal* feeding tubes for long term use, class IIb (GMDN-code 14221 / Nasogastric feeding tube)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_009 Flocare NG_NI feeding tubes* 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 codes)	Product name	Product Type	First Product LOT	Production site
594566	94566	Flocare® PUR tube	ENFit CH5-50CM	201510N99	NP Wuxi
594567	94567	Flocare® PUR tube	ENFit CH6-60CM	201510L39	NP Wuxi
594568	94568	Flocare® PUR tube	ENFit CH6-110CM	201510L49	NP Wuxi
594569	94569	Flocare® PUR tube	ENFit CH8-110CM	201511K19	NP Wuxi
594570	94570	Flocare® PUR tube	ENFit CH10-110CM	201511K29	NP Wuxi
594571	94571	Flocare® PUR tube	ENFit CH12-110CM	201511K39	NP Wuxi
594572	94572	Flocare® PUR tube	ENFit CH14-110CM	201511K49	NP Wuxi
612929	112929	Flocare® PUR tube	ENFit CH10-130CM	201608L09	NP Wuxi
624856	124856	Flocare® PUR tube with guidewire	ENFit/ suction CH14-110CM	1112096745	NP Wuxi
630436	130436	Flocare® PURSOFT tube	ENFit CH4-40CM	1112283163	NP Wuxi
594573	94573	Flocare® PURSOFT tube	ENFit CH5-40CM	201510P49	NP Wuxi
594574	94574	Flocare® PURSOFT tube	ENFit CH5-60CM	201510P59	NP Wuxi
654098	150498	Flocare® PURSOFT tube	ENFit CH6-40	tbc	NP Wuxi
621541	121541	Flocare® PURSOFT tube	ENFit CH6-60CM	201703K59	NP Wuxi
594575	94575	Flocare® PURSOFT tube	ENFit CH8-60CM	201510P69	NP Wuxi
594576	94576	Flocare® PURSOFT tube with guidewire	ENFit CH10-90CM	201511L19	NP Wuxi
594577	94577	Flocare® PURSOFT tube with guidewire	ENFit CH10-110CM	201510M59	NP Wuxi
594579	94579	Flocare® PURSOFT tube with guidewire	ENFit CH14-110CM	201511L29	NP Wuxi
594580	94580	Flocare® PURSOFT tube with guidewire	ENFit CH8-125CM	201511L99	NP Wuxi

Product Code (REF)	SAP (logistical codes)	Product name	Product Type	First Product LOT	Production site
622661	122661	Flocare®PURSOFT tube with guidewire	ENFit/ suction CH14-110CM	1112026420	NP Wuxi
594562	94562	Flocare®NUTRISOFT tube with guidewire	ENFit CH18-110CM	201603L99	NP Wuxi
594563	94563	Flocare®NUTRISOFT tube	ENFit CH8-60CM	201604N19	NP Wuxi
594564	94564	Flocare®NUTRISOFT tube with guidewire	ENFit CH10-125CM	201604N29	NP Wuxi
594565	94565	Flocare®NUTRISOFT tube with guidewire	ENFit CH14-110CM	201603M09	NP Wuxi
624618	124618	Flocare®NUTRISOFT tube with guidewire	ENFit/ suction CH14-110CM	1112204817	NP Wuxi
624857	124857	Flocare®NUTRISOFT tube with guidewire	ENFit/ suction CH18-110CM	1112211198	NP Wuxi

Annex B to the Declaration of Conformity (History sheet)

Flocare® Nasogastric/*intestinal* feeding tubes for long term use, class IIb (GMDN-code 14221 / Nasogastric feeding tube)

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_009 Flocare NG_NI feeding tubes* 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 (66211TE01 became obsolete), re-issued on September 12, 2017. Revised on 2 July 2019 for the new Hoofddorp address.

Rev. 009 Inclusion SAP logistical codes

Rev. 008 Inclusion of last batch information – update delisted product list
Inclusion new SKU 654098 (ICC2019-012)

Rev. 007 Inclusion first batch information suction tubes (ICC2016-029)
Inclusion last batch information (Annex C) for non ENFit devices
Update to new office address from Schiphol to Hoofddorp
Update to ISO13485:2016 and revised CE certificates (new address)

Rev. 006 Inclusion new SKU 630436 Ch4-40 cm PURSoft (ICC2017-007) & inclusion first batch information PUR and PURSoft suction tubes

Rev. 005 Update new CE certificate re-issued 12 September 2017. Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.

Rev. 004 Inclusion new "Suction port" SKUs (ICC2016-029)

Rev. 003 Inclusion new SKU 621541 PURSoft Ch6-60 (ICC2016-022)

Rev. 002 Correction of SKU number of new 130cm PUR tube (ICC2015-012) from 5612929 to 612929 and inclusion of first batch information

Rev. 001 Transfer to Annex II certification (ICC2016-009)/ Replacing DoC "Decl conf NMD 66211TE01_017 Flocare NG feeding tubes"

Inclusion first batch information ENFit products (ICC2013-008 Nexus and ICC2013-019 Co-moulding Nutrisoft Tubes).

ICC2015-012 introduction of new 130cm PUR tube SKU 5612929

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

Flocare® Nasogastric/*intestinal* feeding tubes for long term use, class IIb (GMDN-code 14221 / Nasogastric feeding tube)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_009 Flocare NG_NI feeding tubes* 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 6 months of expiry of last produced batch.

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production site
35203	Flocare® PURSoft	Ch5-40 cm	200902L89	201205N79	NP Wuxi
35204	Flocare® PURSoft	Ch5-60 cm	200902L79	201201M29	NP Wuxi
35205	Flocare® PURSoft	Ch8-60 cm	200901K59	201209L29	NP Wuxi
35212	Flocare® PURSoft M with guide wire	Ch10-90 cm	200901K79	201206K29	NP Wuxi
35213	Flocare® PURSoft M with guide wire	Ch10-110 cm	200901K89	201205M89	NP Wuxi
35214	Flocare® PURSoft M with guide wire	Ch14-110 cm	200901L39	201208L69	NP Wuxi
35215	Flocare® PURSoft M Long with guide wire	Ch8-125 cm	200906L19	201205K59	NP Wuxi
570893	Flocare® PURSoft NGF tube (with radio opaque lines) - ENLock	Ch8-60 cm	201210L49	201510N09	NP Wuxi
570894	Flocare® PURSoft NGF tube (with radio opaque lines) - ENLock	Ch5-40 cm	201210L59	1112042171	NP Wuxi
570895	Flocare® PURSoft M - ENLock (with guide wire)	Ch14-110 cm	201210M39	1112007194	NP Wuxi
570896	Flocare® PURSoft M - ENLock (with guide wire)	Ch10-110 cm	201205L49	201507M99	NP Wuxi
570897	Flocare® PURSoft M - ENLock (with guide wire)	Ch10-90 cm	201210L89	201510M89	NP Wuxi
570898	Flocare® PURSoft M Long - ENLock (with guide wire)	Ch8-125 cm	201210L99	201510K89	NP Wuxi
571460	Flocare® PURSoft NGF tube (with radio opaque lines) - ENLock	Ch5-60 cm	201210M19	201509M19	NP Wuxi
35218	Flocare® PUR tube with guide wire + multi purpose connector	Ch5-50 cm	200902L59	201207K99	NP Wuxi
35219	Flocare® PUR tube with guide wire + multi purpose connector	Ch6-60 cm	200901L09	201207L09	NP Wuxi
35221	Flocare® PUR tube with guide wire + multi purpose connector	Ch6-110 cm	200901L29	201201M19	NP Wuxi
35224	Flocare® PUR tube with guide wire + multi purpose connector	Ch8-110 cm	200901K19	201510Q49	NP Wuxi
35226	Flocare® PUR tube with guide wire + multi purpose connector	Ch10-110 cm	200901K29	201507L19	NP Wuxi
35228	Flocare® PUR tube with guide wire + multi purpose connector	Ch12-110 cm	200902L49	201510K79	NP Wuxi
35229	Flocare® PUR tube with guide wire + multi purpose connector	Ch14-110 cm	200902K19	201511K99	NP Wuxi
35257	Flocare® PUR tube + Male Luer Lock connector	Ch6-110 cm	200904K99	201603L09	NP Wuxi
35258	Flocare® PUR tube + Male Luer Lock connector	Ch8-110 cm	200901M19	201604M79	NP Wuxi
35259	Flocare® PUR tube + Male Luer Lock connector	Ch10-110 cm	200901L89	201604K29	NP Wuxi
35260	Flocare® PUR tube + Male Luer Lock connector	Ch10-130 cm	200901M09	201604M29	NP Wuxi

569298	Flocare®PUR tube - ENLock (with guide wire)	Ch6-110	201210M99	201510M29	NP Wuxi
569299	Flocare®PUR tube - ENLock (with guide wire)	Ch10-110	201205L39	201510Q29	NP Wuxi
569300	Flocare®PUR tube - ENLock (with guide wire)	Ch14-110	201210N19	201511L49	NP Wuxi
569861	Flocare®PUR tube - ENLock (with guide wire)	Ch12-110	201210L19	201510Q39	NP Wuxi
569862	Flocare®PUR tube - ENLock (with guide wire)	Ch8-110	201210L29	201511L39	NP Wuxi
569867	Flocare®PUR tube - ENLock (with guide wire)	Ch5-50 cm	201210L39	201511M69	NP Wuxi
571459	Flocare®PUR tube - ENLock (with guide wire)	Ch6-60	201210M09	201509K29	NP Wuxi
35234	Flocare®NutriSoft	Ch14-110 cm	200908K69	201501K09	NP Wuxi
35236	Flocare®NutriSoft	Ch8-60 cm	200909M09	201604K09	NP Wuxi
35238	Flocare®NutriSoft M with guide wire	Ch10-125 cm	200911K79	201512N39	NP Wuxi
35235	<i>Flocare®NutriSoft</i>	<i>Ch18-110 cm</i>	<i>200909M49</i>	<i>1112189053</i>	<i>NP Wuxi</i>
35239	<i>Flocare®NutriSoft M with guide wire</i>	<i>Ch14-110 cm</i>	<i>200908K59</i>	<i>1112195723</i>	<i>NP Wuxi</i>