



DECLARATION OF CONFORMITY (Medical Devices)
DoC NMD 93928CE02_008 Flocare Enteral Feeding Sets (ENFit)

Nutricia Medical Devices B.V., having its registered office at Taurusavenue 167 / 2132 LS Hoofddorp (The Netherlands), hereby declares that the distributed CE marked products, specified in the annexed product list, are covered by the CE Marking of Conformity 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 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® enteral feeding sets (ENFit) 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, 25 February 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® Enteral feeding sets, class IIa
(GMDN-code 64461 / Enteral feeding noninvasive-component set)**

This product list belongs to the Declaration of Conformity identified by DoC NMD 93928CE02_008 Flocare Enteral Feeding Sets (ENFit) 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.

ENFit FEEDING SETS

Product Code (REF)	SAP (logistical code)	Product name	Product Type	First Product LOT
586484	86484	FLOCARE INFINITY PACK MOBILE SET W/O MP	Infinity (pump)	201606869
590086	90086	FLOCARE INFINITY BOTTLE SET W/O MP	Infinity (pump)	201608509
595349	95349	FLOCARE INFINITY PACK SET W/O DC & W/O MP	Infinity (pump)	201608629
586514	86514	FLOCARE INFINITY PACK SET	Infinity (pump)	201607169
586518	86518	FLOCARE INFINITY PACK TWINLINE SET	Infinity (pump)	201609119
586520	86520	FLOCARE INFINITY PACK MOBILE SET	Infinity (pump)	201606949
589825	89825	FLOCARE INFINITY PACK & BOTTLE SET	Infinity (pump)	201606929
590011	90011	FLOCARE INFINITY TF RES SET 1.3 L	Infinity (pump)	201607S79
590068	90068	FLOCARE INFINITY TF RES SET 2.0 L	Infinity (pump)	201607R39
590084	90084	FLOCARE INFINITY BOTTLE SET	Infinity (pump)	201607179
600103	100103	FLOCARE INFINITY PACK SET W/O DC	Infinity (pump)	201612379
595347	95347	FLOCARE INFINITY PACK SET W/O DC Y-PORT	Infinity (pump)	201612149
601586	101586	FLOCARE INFINITY PACK MOBILE SET Y-PORT	Infinity (pump)	201612189
601587	101587	FLOCARE INFINITY BOTTLE SET Y-PORT	Infinity (pump)	201612129
630599	130599	FLOCARE INFINITY PACK & BOTTLE MOBILE SET	Infinity (pump)	1112370115

Product Code (REF)	SAP (logistical code)	Product name	Product Type	First Product LOT
586460	86460	FLOCARE GRAVITY PACK SET	Gravity	201607159
589755	89755	FLOCARE GRAVITY PACK & BOTTLE SET	Gravity	201608789
589785	89785	FLOCARE GRAVITY TF RES SET 2.0 L	Gravity	201607R29
589827	89827	FLOCARE GRAVITY TF RES SET 1.3 L	Gravity	201608S79
590070	90070	FLOCARE GRAVITY BOTTLE SET	Gravity	201607129
595348	95348	FLOCARE 800 PACK SET W/O MP	F800 (pump)	201610579
586512	86512	FLOCARE 800 PACK SET	F800 (pump)	201612159
589787	89787	FLOCARE 800 TF RES SET 1.3 L	F800 (pump)	201611S39
589789	89789	FLOCARE 800 TF RES SET 2.0 L	F800 (pump)	201611S29
589823	89823	FLOCARE 800 PACK & BOTTLE SET	F800 (pump)	201611529
590082	90082	FLOCARE 800 BOTTLE SET	F800 (pump)	201611529

Annex B to the Declaration of Conformity (History sheet)

**Flocare® Enteral feeding sets, class IIa
(GMDN-code 64461 / Enteral feeding noninvasive-component set)**

This history sheet belongs to the Declaration of Conformity identified by *DoC NMD 93928CE02_008 Flocare Enteral Feeding Sets (ENFit)* 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: 59802CE01, issued for the first time on December 5, 1995, re-issued on December 1, 2004, revised on February 26, 2007, re-issued on November 15, 2007, re-issued on September 1, 2010, revised 30 March 2012, revised 18 June 2012, re-issued on 1 September 2013, revised as certificate number 93928CE01 on 23 March 2016 (certificate 59802CE01 became obsolete), re-issued on September 12, 2017. Revised on 2 July 2019 for the new Hoofddorp address.

Rev. 008 Update GMDN code from 11677 to 64461

Rev. 007 Inclusion SAP logistical codes

Rev. 006 Inclusion of last batch information – update delisted product list

Correction product name of SKU 595347 (add Y port)

Inclusion new SKU 630599 (ICC2019-022)

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

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

Rev. 004 Update new CE certificate re-issued 12 September 2017

Rev. 003 Including first batch information ENFit SKUs ICC2013-008 wave 3 (ICC2016-046 first batch production for ENFit feeding sets). Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.

Rev. 002 Including final ENFit Sets SKUs (ICC2013-008 wave 3) and first batch information

Rev. 001 Transfer to Annex II certification (ICC2016-009). Replacing DoC "DoC NMD 59802CE01 Flocare Enteral Feeding Sets (ENFit)_v002"

Update product name of topfill sets from TF RES Set to TOPFILL RESERVOIR SET (alignment)

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

Flocare® Enteral feeding sets, class IIa (GMDN-code 64461 / Enteral feeding noninvasive-component set)

This Annex belongs to the Declaration of Conformity identified by DoC NMD 93928CE02_008 Flocare Enteral Feeding Sets (ENFit) and specifies the discontinued products within the identified certificate. Product ranges are identified by first and last produced LOT. After shelf life expiration of the last produced LOT, the SKU will be removed from the Declaration of Conformity – discontinued product lists.

TRANSITION (ENFit) FEEDING SETS

Product Code (REF)	Product name	Product Type	First Product LOT	Last product LOT
586459	FLOCARE GRAVITY PACK SET - TRANSITION	Gravity	201506759	1112047258
589754	FLOCARE GRAVITY PACK & BOTTLE SET - TRANSITION	Gravity	201506769	1112060431
589784	FLOCARE GRAVITY TOPFILL RESERVOIR SET 2.0 L - TRANSITION	Gravity	201506S99	201609R39
589826	FLOCARE GRAVITY TOPFILL RESERVOIR SET 1.3 L - TRANSITION	Gravity	201506T39	1112047231
590069	FLOCARE GRAVITY BOTTLE SET - TRANSITION	Gravity	201506779	1112067703
591402	FLOCARE GRAVITY PACK SET LUER FREE - TRANSITION	Gravity	201506799	201612969
591405	FLOCARE GRAVITY PACK & BOTTLE SET LUER FREE - TRANSITION	Gravity	201506809	201701239
586511	FLOCARE 800 PACK SET - TRANSITION	F800 (pump)	201506969	201609389
589756	FLOCARE 800 PACK & BOTTLE SET - TRANSITION	F800 (pump)	201506979	201612949
589786	FLOCARE 800 TOPFILL RESERVOIR SET 1.3 L – TRANSITION	F800 (pump)	201506S89	201701S09
589788	FLOCARE 800 TOPFILL RESERVOIR SET 2.0 L – TRANSITION	F800 (pump)	201506T09	201607R19
590081	FLOCARE 800 BOTTLE SET – TRANSITION	F800 (pump)	201506959	201607849
595166	FLOCARE 800 PACK GIVING SET - TRANSITION	F800 (pump)	201507949	201610249
595173	FLOCARE 800 PACK GIVING SET W/O MP - TRANSITION	F800 (pump)	201508109	201609639
586513	FLOCARE INFINITY PACK SET - TRANSITION	Infinity (pump)	201507209	1112081763
586517	FLOCARE INFINITY PACK TWINLINE SET - TRANSITION	Infinity (pump)	201506989	201612179
586519	FLOCARE INFINITY PACK MOBILE SET - TRANSITION	Infinity (pump)	201506939	1112060441

586521	FLOCARE INFINITY PACK MOBILE SET W/O MP - TRANSITION	Infinity (pump)	201506949	201608469
589824	FLOCARE INFINITY PACK & BOTTLE SET - TRANSITION	Infinity (pump)	201507189	1112070465
589790	FLOCARE INFINITY TOPFILL RESERVOIR SET 1.3 L - TRANSITION	Infinity (pump)	201507R39	1112033549
590012	FLOCARE INFINITY TOPFILL RESERVOIR SET 2.0 L - TRANSITION	Infinity (pump)	201507R79	201610R79
590083	FLOCARE INFINITY BOTTLE SET - TRANSITION	Infinity (pump)	201507119	1112067704
591403	FLOCARE INFINITY PACK SET LUER FREE - TRANSITION	Infinity (pump)	201507289	201701449
591404	FLOCARE INFINITY PACK MOBILE SET LUER FREE - TRANSITION	Infinity (pump)	201507409	201611829
591406	FLOCARE INFINITY PACK & BOTTLE SET LUER FREE - TRANSITION	Infinity (pump)	201507349	1112081784
591408	FLOCARE INFINITY BOTTLE SET LUER FREE - TRANSITION	Infinity (pump)	201507149	1112244559
595168	FLOCARE INFINITY PACK GIVING SET MLL W/O DC - TRANSITION	Infinity (pump)	201506909	201701129
595172	FLOCARE INFINITY BOTTLE GIVING SET - TRANSITION	Infinity (pump)	201506899	201612319
595174	FLOCARE INFINITY PACK GIVING SET W/O DC & W/O MP - TRANSITION	Infinity (pump)	201506829	201701479
595179	FLOCARE INFINITY BOTTLE GIVING SET W/O MP - TRANSITION	Infinity (pump)	201508119	201701169
595181	FLOCARE INFINITY PACK MOBILE GIVING SET - TRANSITION	Infinity (pump)	201506919	201701469
595182	FLOCARE INFINITY PACK MOBILE GIVING SET W/O MP - TRANSITION	Infinity (pump)	201506819	201612309
600099	FLOCARE INFINITY PACK SET W/O DC - TRANSITION	Infinity (pump)	201508419	201612389