



DECLARATION OF CONFORMITY (Medical Devices)

DoC NMD Flocare Access Sterile 93928CE02_007

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, 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® 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:

- Scholle-IPN, Industrieweg 17A, Kampen, The Netherlands
- 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

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)

(Sterile accessories for Flocare® enteral feeding and/or pharmaceutical medication administration systems, class I sterile & class IIa)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD Flocare Access Sterile 93928CE02_007* 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.

(GMDN-code 11675 / Enteral Feeding Bag)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|---|---------------------------|-----------------|-------------------|-----------------|
| 570056 | 70056 | Flocare® Top Fill Reservoir Pack connector 2.0L- with Cross spike adapter | Enteral feeding container | Class I sterile | 201303R89 | NP Wuxi |
| 570139 | 70139 | Flocare® Top Fill Reservoir Pack connector 1.3L –with Cross spike adapter | Enteral feeding container | Class I sterile | 201211S19 | NP Wuxi |

(GMDN-code 11675 / Enteral Feeding Bottle)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|--|---------------------------|-----------------|-------------------|-----------------|
| 35724 | 40455 | Flocare® Container 1.0 l with Pack connector 10x | Enteral feeding container | Class I sterile | PR110299 | IPN CRM |
| 35746 | 40441 | Flocare® Container 0.5 l with Pack connector 10x | Enteral feeding container | Class I sterile | PR110376 | IPN CRM |
| 35767 | 40332 | Flocare® Container 1.0 l with Pack connector 4x | Enteral feeding container | Class I sterile | PR110412 | IPN CRM |

(GMDN-code 60539 / Vial/bottle adaptor, non-hermetic)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|---|-----------------|-----------------|-------------------|-----------------|
| 559943 | 59943 | Flocare® Nutricia Bottle Adapter | Connector | Class I sterile | E201302119 | NP Wuxi |
| 570063 | 70063 | Flocare® Universal adapter - Cross Design | Connector | Class I sterile | E201207119 | NP Wuxi |
| 589740 | 89740 | Flocare® Bolus Adaptor | Adapter – ENFit | Class I sterile | E201511169 | NP Wuxi |

(GMDN-code 64461 / Enteral feeding noninvasive-component set)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|---|--------------|-----------|-------------------|-----------------|
| 569915 | 69915 | Flocare® Two Pack Connector - Cross Spike | Connector | Class IIa | 201210749 | NP Wuxi |

| | | | | | | |
|--------|-------|--------------------|-------|-----------------|-----------|---------|
| 589752 | 89752 | Flocare® Bolus Set | ENFit | Class I sterile | 201512429 | NP Wuxi |
|--------|-------|--------------------|-------|-----------------|-----------|---------|

(GMDN-code 64469 / ENFit/non-ISO80369-standardized linear connector)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|-----------------------------|-------------------|-----------------|-------------------|-----------------|
| 591395 | 91395 | Flocare® PEG Connector CH14 | Connector - ENFit | Class I sterile | E201601139 | NP Wuxi |
| 591396 | 91396 | Flocare® PEG Connector CH18 | Connector - ENFit | Class I sterile | E201601129 | NP Wuxi |
| 591397 | 91397 | Flocare® PEG Connector CH10 | Connector - ENFit | Class I sterile | E201602149 | NP Wuxi |

(GMDN-code 64471 / ENFit/ENFit linear connector)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|-------------------------------|-----------------|-----------------|-------------------|-----------------|
| 625433 | 125433 | Flocare® ENFit Swivel Adapter | Adapter – ENFit | Class I sterile | <i>tdb</i> | NP Wuxi |

(GMDN-code 64593 / Medical/surgical interventional tube/cable securement clip, reusable)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|--|------------------------|-----------------|-------------------|-----------------|
| 35709 | 40448 | Flocare® External Retention Disc (for use with PEG / G-tube Ch10) | ERD - Retention device | Class I sterile | E201412219 | NP Wuxi |
| 35710 | 40449 | Flocare® External Retention Disc (for use with PEG / G-tube Ch14) | ERD - Retention device | Class I sterile | E201202199 | NP Wuxi |
| 35711 | 40450 | Flocare® External Retention Disc (for use with PEG Ch18 / G-tube Ch16/18/20) | ERD - Retention device | Class I sterile | E201204129 | NP Wuxi |
| 666134 | 166134 | Flocare® PEG External Retention Disc Ch14 | ERD - Retention device | Class I sterile | <i>tdb</i> | NP Wuxi |

(GMDN-code 62256 / enteral tube extension, sterile)

| Product Code (REF) | SAP (logistical code) | Product name | Product Type | Class | First Product LOT | Production Site |
|--------------------|-----------------------|------------------------------------|-----------------------|-----------|-------------------|-----------------|
| 591393 | 91393 | Flocare® Extension Set - 100cm | Extension set - ENFit | Class IIa | 201511799 | NP Wuxi |
| 591398 | 91398 | Flocare® Button Extension Set | Extension set - ENFit | Class IIa | 201511619 | NP Wuxi |
| 642515 | 142515 | Flocare® Button Extension Set PLUS | Extension set - ENFit | Class IIa | 1112303178 | NP Wuxi |

Annex B to the Declaration of Conformity (History sheet)

(Sterile accessories for Flocare® enteral feeding and/or pharmaceutical medication administration systems, class I sterile & class IIa)

This history sheet belongs to the Declaration of Conformity identified by *DoC NMD Flocare Access Sterile 93928CE02_007* 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 with reference number 75116CE01, issued for the first time on February 13, 1997, reissued on October 10, 2005, revised on February 26, 2007, reissued on November 15, 2007, reissued on September 1, 2010, reissued on 1 September 2013, revised as certificate number 93928CE01 on 23 March 2016 (certificate 75116CE01 became obsolete), re-issued on September 12, 2017. Revised on 2 July 2019 for the new Hoofddorp address.

Rev. 007 Correction GMDN code containers from 35067 to 11675

Correction GMDN codes other accessories

Removal guide wire to delisted portfolio

Rev. 006 ICC2018-023 New ERD with integrated clamp - REF666134

Rev. 005 Inclusion SAP logistical codes

Rev. 004 Correction to Hoofddorp address in first paragraph

Including first batch information SKU642515

Rev.003 Generic update, removal of obsolete SKUs with last batch information.

ICC2018-016 New SKU 642515 for a longer Button Extension set for UK

Update to new office address from Schiphol to Hoofddorp

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

Rev.002.01 Correction product names SKU625433 (ICC2016-023) to "Flocare® ENFit Swivel Adapter" and correction product names external retention devices from External Retention Device to 'ERD – External Retention Disc'

Rev.002 Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019. Update new CE certificate re-issued 12 September 2017. Update first batch information. Name change supplier IPN CRM to Scholle-IPN (same company, same address). Inclusion new SKU625433 ENFit Swivel Adapter

Rev. 001 Transfer to Annex II certification (ICC2016-009). Replacing DoC "Decl conf NMD Flocare Access Sterile 75116CE01_020"

Inclusion of new ENFit products (ICC2013-008 NEXUS Project) / new DoC lay-out

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

(Sterile accessories for Flocare® enteral feeding and/or pharmaceutical medication administration systems, class I sterile & class IIa)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD Flocare Access Sterile 93928CE02_007* and specifies the discontinued products within the identified certificate. Product ranges are identified by first and last produced LOT. Products will be removed from the discontinued product list after 1 month of expiry of last produced batch.

(GMDN-code 11675 / Enteral Feeding Bags)

| Product Code (REF) | Product name | Product Type | Class | First Product LOT | Last Product LOT | Production Site |
|--------------------|--|---------------------------|-----------------|-------------------|------------------|-----------------|
| 35732 | Flocare® Top Fill reservoir 1.3 L for Pack | Enteral feeding container | Class I sterile | 093317 | 201210T39 | NP Wuxi |
| 35734 | Flocare® Spikeable reservoir 2 L | Enteral feeding container | Class I sterile | 105627 | 201212U29 | NP Wuxi |

(GMDN-code 36057 / Patient feeding bottle)

| Product Code (REF) | Product name | Product Type | Class | First Product LOT | Last Product LOT | Production Site |
|--------------------|-----------------------------|--------------|-----------------|-------------------|------------------|-----------------|
| 00349 | Flocare® Glass Bottle 0.5 L | Container | Class I sterile | 980611 | tbc | IPN CRM |
| 00750 | Flocare® Glass Bottle 0.2 L | Container | Class I sterile | PR070067 | tbc | IPN CRM |

(GMDN-code 46115 / Catheter adaptor, general purpose)

| Product Code (REF) | Product name | Product Type | Class | First Product LOT | Last Product LOT | Production Site |
|--------------------|--|--------------|-----------------|-------------------|------------------|-----------------|
| 03335 | Flocare® Infusion cap | Cap | Class I sterile | 70003-980574 | tbc | IPN CRM |
| 03342 | Flocare® Spikeable cap | Cap | Class I sterile | 70052-980654 | tbc | IPN CRM |
| 550179 | Flocare® Glass bottle cap | Cap | Class I sterile | E201202219 | E201306239 | NP Wuxi |
| 35716 | Flocare® Feeding connector, Ch14 | Connector | Class I sterile | E201105149 | E201303219 | NP Wuxi |
| 35717 | Flocare® Feeding connector, Ch18 | Connector | Class I sterile | E201105209 | E201301159 | NP Wuxi |
| 35718 | Flocare® Feeding connector, Ch10 | Connector | Class I sterile | E201104139 | E201206109 | NP Wuxi |
| 35745 | Flocare® Two Pack Connector | Connector | Class IIa | 200812A59 | 201301639 | NP Wuxi |
| 35772 | Flocare® Universal pack adapter | Connector | Class I sterile | E200906149 | E201207159 | NP Wuxi |
| 35743 | Flocare® MC Pack Adapter | Adapter | Class I sterile | E200812129 | E201205159 | NP Wuxi |
| 35751 | Flocare® Feeding connector Female L.L. | Connector | Class I sterile | E201102109 | E201602109 | NP Wuxi |
| 569863 | Flocare® ENLock Feeding connector Ch10 | Connector | Class I sterile | E201210109 | E201512259 | NP Wuxi |
| 569864 | Flocare® ENLock Feeding connector Ch14 | Connector | Class I sterile | E201210119 | E201512229 | NP Wuxi |
| 569868 | Flocare® ENLock Feeding connector | Connector | Class I sterile | E201210129 | E201508189 | NP Wuxi |

| Ch18 | | | | | | |
|--------|--------------------------------------|---------|-----------------|------------|------------|---------|
| 35744 | Flocare® Bolus Adapter | Adapter | Class I sterile | E200812139 | E201206169 | NP Wuxi |
| 35779 | Flocare® Bolus Adapter non luer | Adapter | Class I sterile | E200812149 | E201405179 | NP Wuxi |
| 569490 | Flocare® MC Slim Pack Adapter | Adapter | Class I sterile | E201208109 | E201512199 | NP Wuxi |
| 569944 | Flocare® Bolus Adapter - Cross Spike | Adapter | Class I sterile | E201210139 | E201603129 | NP Wuxi |

(GMDN-code 11677 / Enteral feeding kit, adult/ paediatric)

| Product Code (REF) | Product name | Product Type | Class | First Product LOT | Last Product LOT | Production Site |
|--------------------|--|-------------------------|-----------------|-------------------|------------------|-----------------|
| 35738 | Flocare® Guide wire Ch5/8 - 60 cm | Introducer | Class I sterile | 200909L29 | 201208L59 | NP Wuxi |
| 35740 | Flocare® Guide wire Ch14/18 - 110 cm | Introducer | Class I sterile | 201005L59 | 201210P09 | NP Wuxi |
| 575041 | Flocare® Guide wire Ch5/8 - 60 cm – Luer Free | Introducer | Class I sterile | 201211M59 | 201411L69 | NP Wuxi |
| 575030 | Flocare® Guide wire Ch14/18 - 110 cm – Luer Free | Introducer | Class I sterile | 201212M79 | tbc | NP Wuxi |
| 03348 | Flocare® Extension set | Extension set | Class IIa | 200911219 | 201603879 | NP Wuxi |
| 35747 | Flocare® Button Luer Lock extension set | Extension set | Class IIa | 200902489 | 201603519 | NP Wuxi |
| 569881 | Flocare® ENLock Extension set 100cm | Extension set | Class IIa | 201210449 | 201510889 | NP Wuxi |
| 576814 | Flocare® Button Extension set - ENLock | Extension set | Class IIa | 201305C09 | 201510719 | NP Wuxi |
| 35773 | Flocare® Bolus set | Set for gravity feeding | Class I sterile | 200705589 | 201604579 | NP Wuxi |