Nutricia Medical Devices BV

DECLARATION OF CONFORMITY (medical devices)

DoC NMD Flocare Access Non sterile_017

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 products distributed with the CE marking of conformity, mentioned in the annex, 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.

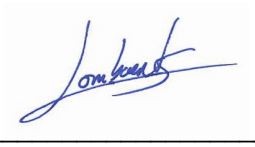
This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:*2016*, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344.

This Declaration of Conformity covers the Flocare® products as specified in the annex belonging to this declaration of conformity, and is valid for all products concerned bearing the CE marking and manufactured at the following production sites:

- Scholle – IPN, Industrieweg 17a, 8263 AB Kampen, The Netherlands
- Nutricia Pharmaceutical (NP) (Wuxi) Co. Ltd. No. 17 XinMing Road, Wuxi, High-tech Development Zone, Jiangsu Province, P.R. China 214111

Hoofddorp, 11 July 2019

RA Manager



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Mr. M.E. Lombaerts

Annexes

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

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Annex A to the Declaration of Conformity (Product list)

(Flocare® Accessories non sterile, class I non sterile devices without a measuring function)

This product list belongs to the declaration of conformity identified by: *DoC NMD Flocare Access Non sterile_017*, and specifies the CE-marked products concerned 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)	Product name	Product Type	First Product LOT	Production site
20548	MCT lubricant	Lubricant for mandrins	PR110265.1	Scholle-IPN
35725	Flocare® Safety clamp (for PEG Ch10/14)	Clamps	E201101129	NP Wuxi
35726	Flocare® Safety clamp (for PEG Ch18)	Clamps	E201102169	NP Wuxi
35727	Flocare® Quick release clamp (for PEG Ch10/14)	Clamps	E201106249	NP Wuxi
35728	Flocare® Quick release clamp (for PEG Ch18)	Clamps	E201103219	NP Wuxi
589739	Flocare® Cap for Male End	Cap - ENFit	E201512239	NP Wuxi
589753	Flocare® Tuohy Borst Adaptor	Connector - ENFit	E201510179	NP Wuxi

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Annex B to the Declaration of Conformity (History sheet)

(Flocare® Accessories non sterile, class I non sterile devices without a measuring function)

This history sheet belongs to the Declaration of Conformity identified by: *DoC NMD Flocare Access Non sterile_017* and specifies the revision history of the Declaration of Conformity, including revisions of the respective Quality System certificate.

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.*

Rev. 017:	*Generic review, removal of obsolete SKUs with last batch information* *Update to new office address from Schiphol to Hoofddorp* *Update to ISO13485:2016 (new address)*
Rev. 016:	Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019. Change supplier name IPN CRM to Scholle-IPN (same company). Inclusion first batch information ENFit accessories. Alignment product names Safety clamp with labelling.
Rev. 015:	-correction revision numbering; not used-
Rev. 014:	Inclusion of new ENFit products (ICC2013-008 NEXUS Project) / new DoC lay-out
Rev. 013:	Removal of SKU 03350 and 35730 of which last batch information has been provided in rev 012. Addition of last batch information delisted SKUs (ICC2011-031)
Rev. 012:	Update DoC due to recertification 1 September 2013 (EN ISO 13485:2012)
Rev. 011:	Addition first batch information ENLock/Salus SKUs ICC2008-022-04 Addition last batch information SKU 35730, 03350.
Rev. 010:	Addition new SKU 576667 (ICC2012-029) Removal SKU 0333 and 03334 produced by IPN CRM of which last batch information has been provided in previous DoC
Rev. 009:	Addition last batch information REF 0333 and 03334 as produced by IPN-CRM (transferred to Wuxi with ICC2010-007 Olympic III) Addition new SKU number 569887 (ICC2008-022 Salus)
Rev. 008:	Removal of products of which last batch info has been provided in previous DoC (REF 35761, 20548, 35778, 35781 from previous supplier IPN HC SA). Removal IPN HC SA from DoC as this production site does not exist anymore; all products are transferred to NP Wuxi or IPN-CRM (ICC2010-007 Olympic project). Addition first batch information REF20548 (transferred from IPN-HC ICC2011-001). Addition REF03333 and 03334 from NP Wuxi (ICC2008-018, 2121536-TDR01-R2).
Rev. 007:	Addition first batches as produced by NP Wuxi for 35725, 35726, 35727, 35728, 35730 and 03350 (ICC2010-007). REFs produced by IPN HC removed from list as last batch info was already included, and first batch info from new manufacturer NP Wuxi is included with rev 007. Correction manufacturer for REF20548: IPN-CRM instead of NP Wuxi (incorrect)
Rev. 006:	Cessation of IPN-HC as subcontractor (ICC2010-007, Olympic III) Addition of Nutricia Pharmaceutical as subcontractor (ICC2010-007, Olympic III) Elimination of CC 35729
Rev. 005:	Added: last lot number 35761. Eliminated: IPN HC products that have been provided with the last product number in the previous DoC Eliminated: “, amended by 2007/47EC of 5 September 2007.”” Changed: “exhibt 1” into “the annex”
Rev. 004:	Addition of text: “, amended by 2007/47EC of 5 September 2007” Change of PackOMed into IPN CRM
Rev. 003:	Addition of 35778 and 35781 to product list
Rev. 002:	Discontinuation of various products

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

(Flocare® Accessories non sterile, class I non sterile devices without a measuring function)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD Flocare Access Non sterile_017* 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 month of expiry of last produced batch.

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production site
03333	Flocare® Cap for male Luer lock	Caps	E200812109	E200902149	NP Wuxi
03334	Flocare® Flush device	Female-female luer lock	E200812119	E201203159	NP Wuxi
35778	*Flocare® Tuohy borst adaptor for Flocare DUO-tube*	*Connector*	*201307249*	*E201505179*	*NP Wuxi*
35781	*Flocare® Bengmark DUO-tube SA Ch9 removal tube*	*Removal Tube*	*n/a*	*never produced by NP Wuxi*	*NP Wuxi*
569887	*Flocare® ENLock step connector (2x50)*	*Connector*	*E201207139*	*E201604199*	*NP Wuxi*
576667	*Flocare® 5-step connector purple (2x50)*	*Connector*	*E201209169*	*E201605159*	*NP Wuxi*