

‘DoC2021270 FLOCARE NASAL TUBES’

Manufacturer name & registered place of business

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp, The Netherlands

SRN

NL-MF-000012729

Risk Class

IIb

General product (device family) name

Nasal Tubes

Product sub-groups (if applicable)

PUR, PURSoft, Nutrisoft, Bengmark NI

Product variants

See attached appendix Product List

Conformity assessment procedure

MDR EU 2017/745, Annex IX (I, II.4, III)

Common specification

n/a

Notified Body and ID #

DEKRA Certification, NL #0344

Certificate # and validity

2262711CE02 / exp 1 Nov 2027

DoC revision

Rev 003

DoC validity

1 Nov 2027

I declare under our sole responsibility that the medical device(s) covered by the present declaration meet the provisions of the Medical Device Regulation EU 2017/745 and that we are solely responsible for issuing this EU Declaration of Conformity.

This Declaration of Conformity covers the **Flocare® Nasal Feeding Tubes family** as specified in the product list below 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, PRC

Place & date of issue: HOOFFDORP, 17 October 2023



Signature:

Position: Global Regulatory Manager, PRRC

Name: Mr. ME Lombaerts, MSc.

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturers name regardless whether these operations are carried out by the manufacturer or on his behalf by a third party.

PRODUCT LIST

Product Catalogue number (SKU/REF)	Product SAP code (logistical/ local ref number)	Product name	GMDN	Basic UDI-DI	First product LOT	Last product LOT (if discontinued)
NASAL TUBES – NUTRISOFT (Iib)						
594563	94563	FLOCARE NUTRISOFT TUBE CH8-60CM	14221	8716900NUTRI FEEDTUBER5	101255415	n/a
594564	94564	FLOCARE NUTRISOFT TUBE M CH10-125CM			101255413	n/a
594565	94565	FLOCARE NUTRISOFT TUBE M CH14-110CM			101255414	n/a
695648	195648	<i>FLOCARE NUTRISOFT TUBE CH17-110CM</i>			101314901	n/a
594562	94562	FLOCARE NUTRISOFT TUBE CH18-110CM			101246482	101291987
624618	124618	FLOCARE NUTRISOFT TUBE CH14-110CM SUCTION/GW		8716900DECO MFEEDTUBE9E	101227471	n/a
624857	124857	FLOCARE NUTRISOFT TUBE CH18-110CM SUCTION/GW			101249505	101303849
695649	195649	<i>FLOCARE NUTRISOFT TUBE CH17-110CM SUCTION/GW</i>			101314900	n/a
NASAL TUBES – PUR (Iib)						
594566	94566	FLOCARE PUR TUBE CH5-50CM	14221	8716900PURFE EDTUBEDN	101271876	n/a
594567	94567	FLOCARE PUR TUBE CH6-60CM			101227468	n/a
594568	94568	FLOCARE PUR TUBE CH6-110CM			101226718	n/a
594569	94569	FLOCARE PUR TUBE CH8-110CM			101229121	n/a
594570	94570	FLOCARE PUR TUBE CH10-110CM			101226719	n/a
612929	112929	FLOCARE PUR TUBE CH10-130CM			101280609	n/a
594571	94571	FLOCARE PUR TUBE CH12-110CM			101235868	n/a
594572	94572	FLOCARE PUR TUBE CH14-110CM			101226720	n/a
624856	124856	FLOCARE PUR TUBE CH14-110CM SUCTION/GW		8716900DECO MFEEDTUBE9E	101240068	n/a
NASAL TUBES – PURSOFT (Iib)						
682968	182968	FLOCARE PURSOFT TUBE CH4-40CM	14221		101246530	n/a

Print date: 17/10/2023

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Not applicable to Records.

594573	94573	FLOCARE PURSOFT TUBE CH5-40CM		8716900PURS OFTFEEDTUBE PM	101246479	n/a
594574	94574	FLOCARE PURSOFT TUBE CH5-60CM			101227470	n/a
654098	154098	FLOCARE PURSOFT TUBE CH6-40CM			101246485	n/a
621541	121541	FLOCARE PURSOFT TUBE CH6-60 W/O GUIDEWIRE			101257124	n/a
594575	94575	FLOCARE PURSOFT TUBE CH8-60CM			101246527	n/a
594580	94580	FLOCARE PURSOFT TUBE M CH8-125CM			101235852	n/a
594576	94576	FLOCARE PURSOFT TUBE M CH10-90CM			101268177	n/a
594577	94577	FLOCARE PURSOFT TUBE M CH10-110CM			101246526	n/a
594579	94579	FLOCARE PURSOFT TUBE M CH14-110CM			101227469	n/a
622661	122661	FLOCARE PURSOFT TUBE M CH14-110CM/SUCTION			8716900DECO MFEEDTUBE9E	101249499
NASAL TUBES – BENGMARK NI (Iib)						
594824	94824	FLOCARE BENGMARK NI TUBE CH8-145CM	16798	8716900BENG MARKFEEDTUBE2N	101271881	n/a
594825	94825	FLOCARE BENGMARK NI TUBE CH10-145CM			101235850	n/a

Revision history

003 ICC2022-003 Change Ch-size labelling of NutriSoft tubes Ch18 to CH17 (including last batch information Ch18 594562 & 624857 as being replaced by new SKUs Ch17 695648 & 695649). Completion of all first batch information.

002 correction EMDN code 14211 to 14221 as per EMDN codes and definitions and inclusion first batch information various SKUs

001 initial release

000 draft for certification review

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