

‘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, Benchmark 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 002

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, 3 November 2022



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 manufacturer's 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 | 8716900NUTRIFEE DTUBER5 | 1012554 15 | n/a |
| 594564 | 94564 | FLOCARE NUTRISOFT TUBE M CH10-125CM | | | 1012554 13 | n/a |
| 594565 | 94565 | FLOCARE NUTRISOFT TUBE M CH14-110CM | | | 1012554 14 | n/a |
| 594562 | 94562 | FLOCARE NUTRISOFT TUBE CH18-110CM | | | 1012464 82 | n/a |
| 624618 | 124618 | FLOCARE NUTRISOFT TUBE CH14-110CM SUCTION/GW | | | 8716900DECOMFE EDTUBE9E | 1012274 71 |
| 624857 | 124857 | FLOCARE NUTRISOFT TUBE CH18-110CM SUCTION/GW | | 1012495 05 | | n/a |
| NASAL TUBES – PUR (Iib) | | | | | | |
| 594566 | 94566 | FLOCARE PUR TUBE CH5-50CM | 14221 | 8716900PURFEEDT UBEDN | tbd | n/a |
| 594567 | 94567 | FLOCARE PUR TUBE CH6-60CM | | | 1012274 68 | n/a |
| 594568 | 94568 | FLOCARE PUR TUBE CH6-110CM | | | 1012267 18 | n/a |
| 594569 | 94569 | FLOCARE PUR TUBE CH8-110CM | | | 1012291 21 | n/a |
| 594570 | 94570 | FLOCARE PUR TUBE CH10-110CM | | | 1012267 19 | n/a |
| 612929 | 112929 | FLOCARE PUR TUBE CH10-130CM | | | tbd | n/a |
| 594571 | 94571 | FLOCARE PUR TUBE CH12-110CM | | | 1012358 68 | n/a |
| 594572 | 94572 | FLOCARE PUR TUBE CH14-110CM | | | 1012267 20 | n/a |
| 624856 | 124856 | FLOCARE PUR TUBE CH14-110CM SUCTION/GW | | 8716900DECOMFE EDTUBE9E | 1012400 68 | n/a |
| NASAL TUBES – PURSOFT (Iib) | | | | | | |
| 682968 | 182968 | FLOCARE PURSOFT TUBE CH4-40CM | 14221 | 8716900PURSOFTF EEDTUBEPM | 1012465 30 | n/a |
| 594573 | 94573 | FLOCARE PURSOFT TUBE CH5-40CM | | | 1012464 79 | n/a |
| 594574 | 94574 | FLOCARE PURSOFT TUBE CH5-60CM | | | 1012274 70 | n/a |

Print date: 11/01/2023

Printed documents are considered uncontrolled. If printed and not stamped 'controlled document', this document is only valid on the print date
Not applicable to Records.

EU MDR 2017/745 Declaration of Conformity

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NMD-FOR-423-04

Version: 1.0

Date of issue:
15 Oct 2021

Date of Next Review:
15 Oct 2023

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|---|--------|--|-------|-------------------------------|---------------|-----|
| 654098 | 154098 | FLOCARE PURSOFT TUBE CH6-40CM | | | 1012464 85 | n/a |
| 621541 | 121541 | FLOCARE PURSOFT TUBE CH6-60 W/O GUIDEWIRE | | | 1012571 24 | n/a |
| 594575 | 94575 | FLOCARE PURSOFT TUBE CH8-60CM | | | 1012465 27 | n/a |
| 594580 | 94580 | FLOCARE PURSOFT TUBE M CH8-125CM | | | 1012358 52 | n/a |
| 594576 | 94576 | FLOCARE PURSOFT TUBE M CH10-90CM | | | tbd | n/a |
| 594577 | 94577 | FLOCARE PURSOFT TUBE M CH10-110CM | | | 1012465 26 | n/a |
| 594579 | 94579 | FLOCARE PURSOFT TUBE M CH14-110CM | | | 1012274 69 | n/a |
| 622661 | 122661 | FLOCARE PURSOFT TUBE M CH14-110CM/SUCTION | | 8716900DECOMFE EDTUBE9E | 1012494 99 | n/a |
| NASAL TUBES – BENCHMARK NI (Iib) | | | | | | |
| 594824 | 94824 | FLOCARE BENCHMARK NI TUBE CH8-145CM | 16798 | 8716900BENGMAR KFEEDTUBE2N | tbd | n/a |
| 594825 | 94825 | FLOCARE BENCHMARK NI TUBE CH10-145CM | | | 1012358 50 | n/a |

Revision history

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

Print date: 11/01/2023

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