

 <p>NUTRICIA LIFE-TRANSFORMING NUTRITION NUTRICIA MEDICAL DEVICES B.V.</p>	<h2 style="text-align: center;">EU MDR 2017/745</h2> <h3 style="text-align: center;">Declaration of Conformity</h3> <p style="text-align: center;">‘DoC2021270 FLOCARE NASAL TUBES’</p>	NMD-FOR-423-04
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<p>Manufacturer name & registered place of business</p> <p>SRN</p> <p>Risk Class</p> <p>General product (device family) name</p> <p>Product sub-groups (if applicable)</p> <p>Product variants</p> <p>Conformity assessment procedure</p> <p>Common specification</p> <p>Notified Body and ID #</p> <p>Certificate # and validity</p> <p>DoC revision</p> <p>DoC validity</p>	<p>Nutricia Medical Devices B.V.</p> <p>Taurusavenue 167</p> <p>2132 LS Hoofddorp, The Netherlands</p> <p>NL-MF-000012729</p> <p>IIb</p> <p>Nasal Tubes</p> <p>PUR, PURSoft, Nutrisoft, Benchmark NI</p> <p>See attached appendix Product List</p> <p>MDR EU 2017/745, Annex IX (I, II.4, III)</p> <p>n/a</p> <p>DEKRA Certification, NL #0344</p> <p>2262711CE02 / exp 1 Nov 2027</p> <p>Rev 001 – initial release MDR certification</p> <p>1 Nov 2027</p>
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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: HOOFFDDORP, 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 manufacturers name regardless whether these operations are carried out by the manufacturer or on his behalf by a third party.

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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	14211	8716900NUTRIFEE DTUBER5	tbd	n/a
594564	94564	FLOCARE NUTRISOFT TUBE M CH10-125CM			tbd	n/a
594565	94565	FLOCARE NUTRISOFT TUBE M CH14-110CM			tbd	n/a
594562	94562	FLOCARE NUTRISOFT TUBE CH18-110CM			tbd	n/a
624618	124618	FLOCARE NUTRISOFT TUBE CH14-110CM SUCTION/GW		8716900DECOMFE EDTUBE9E	1012274 71	n/a
624857	124857	FLOCARE NUTRISOFT TUBE CH18-110CM SUCTION/GW			tbd	n/a
NASAL TUBES – PUR (Iib)						
594566	94566	FLOCARE PUR TUBE CH5-50CM	14211	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	14211	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

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654098	154098	FLOCARE PURSOFT TUBE CH6-40CM			tbd	n/a
621541	121541	FLOCARE PURSOFT TUBE CH6-60 W/O GUIDEWIRE			tbd	n/a
594575	94575	FLOCARE PURSOFT TUBE CH8-60CM			tbd	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
NASAL TUBES – BENGMARK NI (Iib)						
594824	94824	FLOCARE BENGMARK NI TUBE CH8-145CM	16798	8716900BENGMAR KFEEDTUBE2N	tbd	n/a
594825	94825	FLOCARE BENGMARK NI TUBE CH10-145CM			tbd	n/a

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