

Manufacturer name & registered place of business	Nutricia Medical Devices B.V. Taurusavenue 167 2132 LS Hoofddorp, The Netherlands
SRN	NL-MF-000012729
Risk Class	class Is (gravity sets) class IIa (pump sets) class Is (extension sets, swivel adaptor, two pack connector)
General product (device family) name	Giving Sets and Accessories
Product sub-groups (if applicable)	Gravity sets, Infinity pump sets, caps, extension sets, swivel adaptor, two pack connector
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	2262711CE01 exp 27JUL2027
DoC revision	Rev 001 (initial release)
DoC validity	10AUG2023

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® Giving Sets and Accessories** 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: HOOFDDORP, 10AUG2022

Nutricia Medical Devices BV
Taurusavenue 167, 2132 LS Hoofddorp
The Netherlands

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.

Print date: 10/08/2022	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.
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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)
GRAVITY GIVING SETS (class Is)						
586460	86460	FLOCARE GRAVITY PACK SET	64461	8716900ENTGRAVITYSETH7	tbd	n/a
589755	89755	FLOCARE GRAVITY PACK & BOTTLE SET			tbd	n/a
589785	89785	FLOCARE GRAVITY TF RES SET 2.0			tbd	n/a
589827	89827	FLOCARE GRAVITY TF RES SET 1.3			tbd	n/a
590070	90070	FLOCARE GRAVITY BOTTLE SET			tbd	n/a
589752	89752	FLOCARE BOLUS SET		8716900ENTBOLUSSETAE	tbd	n/a
PUMP GIVING SETS (IIa)						
595347	95347	FLOCARE INFINITY PACK SET W/O DC Y-PORT	64461	8716900PUMPFEEDSETEA	tbd	n/a
595349	95349	FLOCARE INFINITY PACK SET W/O DC & W/O MP			tbd	n/a
600103	100103	FLOCARE INFINITY PACK SET W/O DC			tbd	n/a
586514	86514	FLOCARE INFINITY PACK SET			tbd	n/a
586518	86518	FLOCARE INFINITY PACK TWINLINE SET			tbd	n/a
594569	86520	FLOCARE INFINITY PACK MOBILE SET			tbd	n/a
586484	86484	FLOCARE INFINITY PACK MOBILE SET W/O MP			tbd	n/a
601586	101586	FLOCARE INFINITY PACK MOBILE SET Y-PORT			tbd	n/a
630599	130599	FLOCARE INFINITY PACK & BOTTLE MOBILE SET			tbd	n/a
589825	89825	FLOCARE INFINITY PACK & BOTTLE SET			tbd	n/a
590084	90084	FLOCARE INFINITY BOTTLE SET			tbd	n/a
590086	90086	FLOCARE INFINITY BOTTLE SET W/O MP			tbd	n/a
601587	101587	FLOCARE INFINITY BOTTLE SET Y-PORT			tbd	n/a

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EU MDR 2017/745
Declaration of Conformity
'DoC2021271 FLOCARE GIVING SETS AND ACCESSORIES'

NMD-FOR-423-04
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Date of issue: 15 Oct 2021
Date of Next Review: 15 Oct 2023
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590011	90011	FLOCARE INFINITY TF RES SET 1.3			tbd	n/a
590068	90068	FLOCARE INFINITY TF RES SET 2.0			tbd	n/a
GIVING SETS ACCESSORIES (Is)						
682967	182967	FLOCARE BUTTON EXTENSION SET PLUS	62256	8716900ENTEXTENSIONSETC9	tbd	n/a
591393	91393	FLOCARE EXTENSION SET - 100CM			tbd	n/a
591398	91398	FLOCARE BUTTON EXTENSION SET			tbd	n/a
570056	70056	FLOCARE TF RES PACK CONN 2.0L - cross	11675	8716900ENTRESE RVOIREC	tbd	n/a
570139	70139	FLOCARE TF RES PACK CONN 1.3L - cross			tbd	n/a
569915	69915	FLOCARE CONN TWO PACK - Cross spike	64461	8716900ENTTWO PACKRT	tbd	n/a

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