

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

NMD-FOR-423-04

Version: 1.0

Date of issue:  
15 Oct 2021

Date of Next Review:  
15 Oct 2023

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**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 (accessories: extension sets, TopFill reservoir pack connector, two pack connector)

**General product (device family) name**  
**Product sub-groups (if applicable)**

Flocare Giving Sets and Accessories  
Gravity sets, Infinity pump sets, extension sets, accessories

**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 rev 0 / exp 27JUL2027

**DoC revision**

Rev 003 (*inclusion site address*)

**DoC validity**

27JUL2027

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.  
No. 17, Xin Ming Road High Tech Development Zone Jiangshu Province 214111 Wuxi City, China

Place & date of issue: HOOFFDORP, 14 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.

Print date: 15/11/2022

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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)
<b>GRAVITY GIVING SETS (class Is)</b>						
586460	86460	FLOCARE GRAVITY PACK SET	64461	8716900ENTGRAVITYSETH7	101227480	n/a
589755	89755	FLOCARE GRAVITY PACK & BOTTLE SET			101235663	n/a
589785	89785	FLOCARE GRAVITY TF RES SET 2.0			101224523	n/a
589827	89827	FLOCARE GRAVITY TF RES SET 1.3			101218065	n/a
590070	90070	FLOCARE GRAVITY BOTTLE SET			101231366	n/a
589752	89752	FLOCARE BOLUS SET		8716900ENTBOLUSSETAE	101224522	n/a
<b>PUMP GIVING SETS (IIa)</b>						
595347	95347	FLOCARE INFINITY PACK SET W/O DC Y-PORT	64461	8716900PUMPFEEDSETEA	101227467	n/a
595349	95349	FLOCARE INFINITY PACK SET W/O DC & W/O MP			101224524	n/a
600103	100103	FLOCARE INFINITY PACK SET W/O DC			101227486	n/a
586514	86514	FLOCARE INFINITY PACK SET			101223511	n/a
586518	86518	FLOCARE INFINITY PACK TWINLINE SET			101227483	n/a
586520	86520	FLOCARE INFINITY PACK MOBILE SET			101223513	n/a
586484	86484	FLOCARE INFINITY PACK MOBILE SET W/O MP			101227485	n/a
601586	101586	FLOCARE INFINITY PACK MOBILE SET Y-PORT			101227484	n/a
630599	130599	FLOCARE INFINITY PACK & BOTTLE MOBILE SET			tbd	n/a
589825	89825	FLOCARE INFINITY PACK & BOTTLE SET			101223512	n/a
590084	90084	FLOCARE INFINITY BOTTLE SET			101224520	n/a
590086	90086	FLOCARE INFINITY BOTTLE SET W/O MP			101235849	n/a
601587	101587	FLOCARE INFINITY BOTTLE SET Y-PORT			101235862	n/a

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 <p><b>NUTRICIA</b> LIFE-TRANSFORMING NUTRITION NUTRICIA MEDICAL DEVICES B.V.</p>	<b>EU MDR 2017/745</b>		NMD-FOR-423-04	
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590011	90011	FLOCARE INFINITY TF RES SET 1.3			101223 509	n/a
590068	90068	FLOCARE INFINITY TF RES SET 2.0			101224 525	n/a
688270	188270	FLOCARE INFINITY PACK & BOTTLE SET W/O DC			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			101227 474	n/a
591398	91398	FLOCARE BUTTON EXTENSION SET			101217 842	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			101246 535	n/a
569915	69915	FLOCARE CONN TWO PACK - Cross spike	64461	8716900ENTTWO PACKRT	101227 473	n/a

Revision history

003 Inclusion production site address on request of CIBG Farmatec - Ministry of Health, Welfare and Sport

002 Inclusion new SKU688270. Added first batch information. Correction typing error SKU reference 594569 to 586520 (SAP86520 and product name were correct)

001 initial release

000 draft for certification review

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