

Manufacturer name & registered place of business	Nutricia Medical Devices B.V. Taurusavenue 167 2132 LS Hoofddorp, The Netherlands
SRN	NL-MF-000012729
Risk Class	Is
General product (device family) name	Flocare Containers
Product sub-groups (if applicable)	-
Product variants	0.5 & 1.0L - See attached appendix Product List
Conformity assessment procedure	MDR EU 2017/745, Article 52 paragraph 7 (Chapter I and III of Annex IX)
Common specification	n/a
Notified Body and ID #	DEKRA Certification, NL #0344
Certificate # and validity	2262711CE03 / exp 22 Sept 2027
DoC revision	Rev 0
DoC validity	5 yr (till 22 Sept 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® Container 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:

- IPN Scholle (also trading as Cura Packaging BV), Kampen, Netherlands

Place & date of issue: HOOFFDORP, 26 SEP 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.

	EU MDR 2017/745 Declaration of Conformity 'DoC2021273 FLOCARE CONTAINERS'	NMD-FOR-423-04
		Version: 1.0
		Date of issue: 15 Oct 2021
		Date of Next Review: 15 Oct 2023
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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)
35724	40455	Flocare Container 1.0 l (with cap)	11675	8716900ENTC ONTAINER3Q	KM05704-001	n/a
35746	40441	Flocare Container 0.5 l (with cap)			KM05651-001	n/a

Print date: 26/09/2022	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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