

Declaration of Compliance

This declaration deals with the following product:

Supplemental Nursing System

Article No.	Description
101043649	Supplemental Nursing System
101043650	Supplemental Nursing System

Food Contact Material Article List:

Article No.	Description	Material	Contact Surface-to-Volume Ratio applied
811.0021	Milk bottle 150ml	Polypropylene	134 cm ² / 150 ml
200.2714	Multi-Lid	Polypropylene	10.5 cm ² / 100 ml
101044080	TwistLok Lid	Polypropylene	35 cm ² / 150 ml
101044084	TwistLok Connector	ABS	2.3 cm ² / 150 ml
101044085	TwistLok Tube	Silicone	10 cm ² / 150 ml
101045022	Valve	Silicone	6.6 cm ² / 150 ml

In accordance with the declarations of our raw material suppliers and our test results, Medela AG confirms compliance with following Regulations and Standards:

- EU Framework Regulation on materials and articles intended for food contact: (EC) No 1935/2004
- Commission Regulation (EC) No 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food.
- Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come in contact with food
- COMMISSION REGULATION (EC) No 1895/2005 - Restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
- Swiss Ordinance on Food Contact Materials SR 817.023.21
- German BfR Recommendation XV (silicones)
- Japanese Food Sanitation Act No. 233 of 1947 (update of 2021 – the materials used for the food-contact parts are on the positive list)
- The Materials and Articles in Contact with Food (England) Regulations 2012 (UK Statutory Instruments 2012 No. 2619)
- The Materials and Articles in Contact with Food (Wales) Regulations 2012 (UK Statutory Instruments 2012 No. 2705)

Information concerning substances with specific migration limits (SML)

Substances subject to SML values are used and declared, the fulfilment of the limits is confirmed for the stated types of food simulant and in the conditions of application. These statements are based on the documentation of the issuer of the declaration of compliance. Supporting documents are available and can be disclosed to the Competent Authority on request.

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits according to Commission Regulation (EU) No 10/2011 and the Swiss Ordinance on Food Contact Materials.

Based on worst foreseeable assumptions, migration testing have been performed under the following conditions:

- EU: Food Simulant D1 (Ethanol 50% v/v) (Thermoplastic parts)
- EU: Food Simulant E (Tenax) (Silicone parts)
- Repeated use condition: migration test carried out three times on a single sample
- Test time (representative of the worst foreseeable contact duration): 1 hour
- Test temperature: 40°C

To the best of our knowledge, based on the information given in our supplier's declarations of compliance and/or confidentiality agreements, we can confirm that there might be some Dual Use Additives present in the food contact products. Supporting documents are available and can be disclosed to the Competent Authority on request.

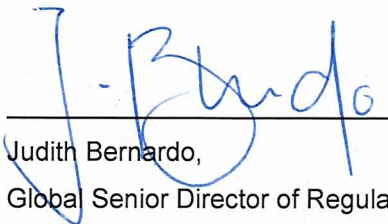
Specification of the application

Breast milk and other liquids of similar consistency are the types of food intended to come into contact with the product. Supplemental Nursing System is intended to be used to feed infants and small children who have a higher consumption of food per kilogram bodyweight than adults and do not yet have a diversified nutrition.

This declaration is valid only when the product is used according to the Instruction for Use, provided that the handling and storage conditions are also appropriate for preservation of the material's specific characteristics.

This declaration will be reviewed when changes to the product materials or the relevant Regulations or Standards occur.

Authorised Signatories:



Judith Bernardo,
Global Senior Director of Regulatory Affairs
Baar/ Switzerland



Bianca Hedari,
Global Senior Director Quality
Baar/ Switzerland

This Declaration of Conformity is effective from: 2023-01-19