

## Declaration of Compliance

This declaration deals with the following products:

### Hands-free Breast Shields and Membrane

Article No.	Description
101045039	Hands-free breast shield 21mm DE FR NL IT PL CS
101045040	Hands-free breast shield 21mm EN ES PT SV DA NO
101045041	Hands-free breast shield 21mm EN ZH TR
101045050	Hands-free breast shield 24mm DE FR NL IT PL CS
101045051	Hands-free breast shield 24mm EN ES PT SV DA NO
101045052	Hands-free breast shield 24mm EN ZH TR
101045055	Hands-free breast shield 27mm DE FR NL IT PL CS
101045056	Hands-free breast shield 27mm EN ES PT SV DA NO
101045057	Hands-free breast shield 27mm EN ZH TR
101045060	Hands-free membrane DE FR NL IT PL CS
101045062	Hands-free membrane EN ES PT SV DA NO
101045063	Hands-free membrane EN ZH TR

### Food Contact Material Articles List:

Article No.	Description	Material	Applied Contact Surface-to-Volume Ratio
101044100	Seal (soft component)	Thermoplastic elastomer	103 cm <sup>2</sup> / 150 ml
101044583	Shell (hard component)	Polypropylene	
101044097	Breast Shield 21 mm	Polypropylene	121cm <sup>2</sup> / 150 ml
101044098	Breast Shield 24 mm		123 cm <sup>2</sup> / 150 ml
101044712	Breast Shield 27mm		127 cm <sup>2</sup> / 150 ml
101044099	Membrane	Silicone	47 cm <sup>2</sup> / 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

- 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)
- Swiss Ordinance on Food Contact Materials SR 817.023.21
- GB 4806.1-11 2016 Food Safety National Standards Food Contact Materials and Products General Safety Requirements
- GB 4806.7-2016 National Food Safety Standard- Plastic Materials and Articles used in Food-contact
- GB 4806.11-2016 National Food Safety Standard-Food contact with rubber materials and products
- GB 9685-2016 National Food Safety Standard: Standard for the Use of Additives in Food Contact Materials
- GB 31603-2015 National Food Safety Standard – General Health Code for Production of Food-contacted Materials and Products.
- German BfR Recommendation XV (silicone)

#### Information concerning substances with specific migration limits (SML)

Substances subject to SML are used and declared, the fulfilment of the limits is confirmed for the stated types of food simulant and in the conditions of intended use. 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:

- Stimulant  
EU: Food Simulant D1 (Ethanol 50% v/v) acc. (EU)10/2011 , for parts made of PP and Si : because-KEG2003H does not degraded in this simulant)  
China: Food Simulant D1 (Ethanol 50% v/v) acc. GB 4806 series
- Test time (depending on the intended contact duration): 24 hours or 10 days
- Test temperature: 40°C

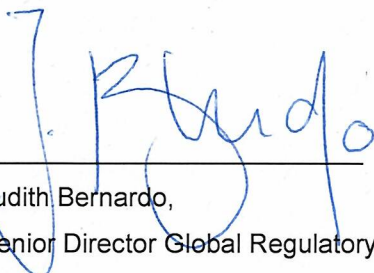
To the best of our knowledge, based on the information given in our supplier's declarations of compliance and/or confidentiality agreements, we can confirm that there might be some Dual Use Additives present in the food contact products. Supporting documents are available and can be disclosed to the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

#### Specification of the application

Breast milk is the type of food intended to come into contact with the product. The product is safe for short time application at up to 40°C. Our products are intended to be used to pump breast milk 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.



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