

DECLARATION OF CONFORITY FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFF

Hereby, **VMECA** declares that, in the conditions of use foreseen and foreseeable, and in the condition in which are market, the articles

“Vacuum Pad for foodstuff”,

It is suitable for repeated use in contact with food, and storing long-term in room temperature (15°C), including heating it up to 40°C for up to 10 days. (Min operation temp: -70°C)

are compliant

to all relevant legislative dispositions, with specific reference to the European and Extra-European Community legislations:

- (EC) 1935/2004 Regulation and subsequent updates and amendments;
- (EC) 2023/2006 Regulation and subsequent updates and amendments;
- FDA (USA) Regulation, Title 21, Federal Regulation Code (CFR) 177.2600

The silicon material is manufactured with the following materials and substances:

- Siloxanes and Silicones, di-Me, Me vinyl, vinyl group-terminated
- Silicon dioxide
- Siloxanes and Silicones, di-Me, hydroxy-terminated

We declare that: the material contains substances subject to restrictions in the aforementioned legislations, and reflects the global migration limits in the following test conditions:

- BfR Recommendation XV
- BfR Recommendation IX

1. Tests according to BfR Recommendation XV
 - a. Silicone - Peroxides

Method : With reference to European Pharmacopoeia, 1977, p.173.

Test item	Result	Requirement*
Peroxide Value	Absent	Absent
Comment	PASS	

b. Silicone – Extractable Components

Method : With reference to 61. Mitteilung über die Untersuchung von Kunststoffen,
Bundesgesundheitsbl 46 (2003) 362.

Test condition: 40°C for 10 days

Test item	Result(% w/w)	Reporting Limit (% w/w)	Permissible Limit (% w/w)
3% Acetic Acid(W/V) Aqueous Solution	N.D	0.1	0.5
10% ethanol	N.D	0.1	0.5
Comment	PASS	--	--

1. % w/w = percentage of weight by weight
2. ND = Not Detected
3. Permissible Limit is according to BfR Recommendation XV

The article is suitable for contact:

• **With all types of foodstuff**

The company declares the technological suitability of the product for the purpose of which it is intended.

To support what above stated, the company declares to have available to (indicate customer) and the competent Authority:

- Other supporting documentation required in accordance with Reg. FDA (USA) Regulation, Title 21, Federal Regulation Code (CFR) 177.2600
- Other supporting documentation required in accordance with Reg. (EC) 1935/2004 art. 16 paragraph1.

This declaration is valid from the date shown below and must be replaced when there are substantial changes in the production of the material that can change certain essential requirements for compliance or when the aforementioned legislative references are modified in order to require a new verification for compliance purposes.

The company VMECA is equipped with a quality management system certified ISO 9001_2015.

Date : 25 JUNE 2024

Signature



S. D. Park / Director of R&D Dept.