

To: **NIC - DENMARK A/S**  
Grydhøjparken 10  
DK-8381, TILST (DK)

Salerno, 20/02/2024

**Object:** Product declaration of conformity

Medac s.r.l., located in Robert Wenner 52 Street, in Salerno, by this declaration states that the raw material of the products coming with food complies with the following EU/National Regulation/Directive and its amendments.

**1. Products Identification**

1.1 Plastic products

- a) Polystyrene boxes

**2 Applicable EU/National Regulation/Directive and its amendments**

For the products mentioned in points 1.1:

- Regulation EC 10/2011 and amendments (latest 2020/1245 of 2 September 2020)
- Regulation EC 2023/2006,
- Regulation EC 1895/2005,
- European Parliament and Council Directive 94/62/EC (amendments to Directive 2004/12/EC and 2005/20/EC and Regulation 219/2009),
- Regulation EC 1935/2004 Article 3, Article 11, paragraph 5, Article 15 and Article 17 ,
- D.M. 21/03/1973 and its amendments

**3 Constituent material of the products coming with food**

For the products mentioned in point 1.1:

letter a<sup>1</sup>) Polistirene (plastic membrane)

letter a<sup>2</sup>) Polipropilene (sheet)

**4 Non-use of food additives and flavourings**

In the realization of the products described at point 1.1 have not been used food additives (Regulation EC 1333/2008), flavourings or food ingredients with flavouring characteristics (Regulation EC 1334/2008).

**5 Compliance with migration limits**

The products described at point 1.1 comply with the limits of global migration in the following test conditions with simulating liquid (ref. Table I Annex III, Table 1 and Table 2 Annex 5 - Regulation EC 10/2011):

Simulant C)	Ethanol at 20% (v/v)	at 20°C for 10 days
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The overall migration limit, altogether with other specific placed restrictions on the monomers and/or additives into the material, are observed in the conditions of use mentioned above

The products referred to point 1.1 do not release metals and / or primary aromatic amines listed in Annex II of Regulation EC 10/2011.

The products referred to point 1.1 do not release semi-volatile, non - volatile compounds and volatile organic compounds in accordance with Regulation EC 10/2011.

The relationship between the contact surface of the food and the volume used to determine compliance of the material, is calculated on the basis of the relationship area/space of 6 dm<sup>2</sup> per kg of foodstuff.

## 6 Compliance with SML

The materials referred to in point 1.1 letter a<sup>1</sup>) The following substances subject to specific migrations are present:

CAS	Substances	LMS
00016-99-0	Butadiene	QM= 1 mg/kg SML= n.d.
36443-68-2	Trietilenglicole-bis [3-(3-ter-butil-4-idrossi-5metilfeni) propionato)	SML= 9 mg/Kg
110553-27-02	2,4-bis(ottiltiometil)-6-metilfenolo	SML 5 mg/Kg
002082-79-3	3- (3,5 – Di-terz-butil-4-idrossifenil) propionato di ottadecile	SML= 6 mg/Kg
38613-77-3	Difosfonito di tetrakis (2,4-di-terz-butilfenil) - 4,4'-bifenililene	SML= 18 mg/Kg
	Sale di zinco	SML= 5 mg/Kg

The products in the conditions of use referred to point. 12 comply with the limits established by the EC Regulation 10/2011 and amendments (global migration and specific migration limits).

The following substances subject to specific migrations in the materials referred to in point 1.1 letter a<sup>2</sup>) are present:

CAS	PM Ref	Substances	Max contained in the film
=	39090	N,N-bis(2-idrossietil)alchil (C8-C18)ammina	SML=1.2 Max cont. <1
0002082-79-3	68320	3-(3,5-di-terz-butil-4-idrossifenil) propionato di ottadecile	SML=6.0 Max cont. 0.0001
0011097-5909	34690	Carbonato(2-)hexadecahidroxybis(aluminium)hexamagnesium	SML=60 Max cont. 0.75
0119345-01-6	83595	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	SML=18 Max cont. 0.035
182121-12-6	39815	9,9-bis(metossimetil)fluorene	SML=0.05 Max cont. 0.0025
27676-62-6	95360	1,3,5-tris(3,5-di-terz-butil-4- idrossibenzil)-1,3,5-triazin- 2,4,6(1H,3H,5H)-trione	SML=5.0 Max cont. <0.265
0071786-60-2	39120	N,N-bis(2-idrossietil)alchil (C8-C18)amine hydrochlorides	SML=1.20 Max cont. 0.0001
007128-64-5	38560	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML= 0.6 Max. cont n.d.
007128-64-5	19960	Maleic anhydride as maleic acid	SML= 30 Max cont. n.d.
000077-99-6	25600	1,1,1-trimethylpropane	SML= 6 Max cont. n.d.

The products in the conditions of use referred to point.12 comply with the limits established by the EC Regulation 10/2011 and amendments (global migration and specific migration limits).

## 7 Compliance with Regulation EC 1333/2008 “Dual Use Additives”

The materials referred to in point 1.1 letters a<sup>1</sup>), based on our declarations suppliers do not contain substances authorized as “dual use additives”.

In the materials referred to in point 1.1 letter a<sup>2</sup>) are present substances "dual use" (ex Reg. CE 1333/2008 - Reg. CE 1334/2008) in compliance with the regulation EU.10 / 2011 and subsequent updates:

	ADDITIVE
E 551	Silicon dioxide
E 471	Glycerol monostearate
E470a	Sodium, potassium and calcium salts of fatty acids
E330	Citric acid
E173	Aluminium
E171	Titanium dioxide

## 8 Compliance with NIAS (Not intentionally added substances)

With reference to the products referred to in point 1.1 regarding the NIAS, if present, a risk assessment was conducted in accordance with art. 19 of the Regulation 10/2011 / UE and of the art. 3 of Regulation 1935/2004 / EC.

## 9 Compliance with Regulation EC 1895/2005

The products referred to point 1.1 do not contain epoxy derivatives.

## 10 Compliance with Regulation (UE) N. 1169/2011 Annex II

The products referred to points 1.1 are in compliance with reference to the Regulation (EU) No 1169/2011 Annex II as amended, or the food allergens or products derived thereof are not intentionally added for added for their manufacture.

## 11 Products coming with foods classification

The products referred to point 1.1 are intended to come into contact with food products as classified under Regulation EC 10/2011 (ref. Table 2 Annex III): ice cream.

## 12 Suitability for use

The products referred to paragraph 1.1 are:

- suitable to be stored at low temperature together with the food product for period longer than 1 months, at the condition of use - 30° degree temperature,
- not suitable for use in a traditional oven together with the food product.

## 13 Legislative reference of declaration of conformity

This declaration is prepared in accordance to Regulation 1935/2004/EC Annex 16 of the European Community and is intended for companies to whom it is addressed.

## 14 Applicable limits


The use of the industrial or commercial material described in this declaration is subject to technological suitability, in relation to the purpose which is intended the material.

## 15 Declaration validity

This declaration is supported by specific documents/evidence showing the products compliance.

This declaration is valid from the above date and will be replaced in case of relevant changes, in the production of material or the essential requirements for compliance.

**Medac S.r.l.**  
Production Manager  
(D.ssa Francesca Mendozzi)



COMPANY WITH  
MANAGEMENT SYSTEM  
CERTIFIED BY DNV  
ISO 9001 • ISO 14001

