

To: **HADECoup BVBA**  
Steenweg 59  
3540, Herk-de Stad

Salerno, 20/01/2023

**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 Coated paper products:

- a) Drinking paper cups,
- b) Hot drinking paper cups,
- c) Pop Corn paper cups
- d) Paper discs,
- e) Paper seals for ice cream cups,
- f) Cardboard lids,
- g) Ice cream paper cups,
- h) Food paper box

### 1.2 Plastic products (bio polymer)

- i) Plastic Lids for drinking paper cups,
- j) Strong Plastic lids,
- k) Flat and Cupolini Plastic Lids for Paper Ice Cream Cups,
- l) Cardboard plastic spoons

### 1.3 Plastic products

- m) Polystyrene boxes

### 1.4 Paper products

- n) Paper sleeves

### 1.5 Wood products

- o) Cardboard spoons

## 2. Applicable EU/National Regulation/Directive and its amendments

For the products mentioned in points 1.1, 1.2 and 1.3:

- 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

For the products mentioned in point 1.4:

- Regulation EC 2023/2006,



- Regulation EC 1935/2004 Article 3, Article 11, paragraph 5, Article 15 and Article 17,
- D.M. 21/03/1973 and its amendments
- European Parliament and Council Directive 94/62/EC (amendments to Directive 2004/12/EC and 2005/20/EC and Regulation 219/2009),

For the products mentioned in point 1.5:

- Regulation EC 2023/2006,
- Regulation EC 1935/2004 Article 3, Article 11, paragraph 5, Article 15 and Article 17,
- European Parliament and Council Directive 94/62/EC Article 11 (amendments to Directive 2004/12/EC and 2005/20/EC and Regulation 219/2009).
- DGCCRF Note d'information n° 2012-93
- Legislative Decree 152/2006 Article 226 c. 4
- D.M. 21/03/1973 GU n° 104 20/04/1973 and its amendments

### 3. Constituent material of the products coming with food

For the products 1.1): Multilayer paper of virgin cellulose coated on the inner side with PE film. No use of recycled material.

For the products 1.1 letters f), g): E CUP line, multilayer paper of virgin cellulose coated on the inner side with biodegradable film. No use of recycled material.

For the products mentioned in point 1.2:

- letter i) Polystyrene,
- letter j) Moplen,
- letter k) PET, PLA
- letter l<sup>2</sup>) PLA,
- letter l<sup>3</sup>) Mater-bi

For the products mentioned in point 1.3:

- letter m<sup>1</sup>) Polistirene (plastic membrane)
- letter m<sup>2</sup>) Polipropilene (sheet)

For the products mentioned in point 1.4:

- letter n) Label Paper

For the products mentioned in point 1.5:

- letter o) Pine wood and birch wood pulp, without treatments

### 4. Non-use of food additives and flavourings

In the realization of the products described at point 1.1, 1.2, 1.3, 1.4, 1.5 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 and 1.2 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 A)	Ethanol at 10% (v/v)	at 40°C for 10 days
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Simulant B)	Acetic acid at 3% (p/v)	
Simulant D2	Oil	

The products described at point 1.3 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 products described at point 1.4 is manufactured with raw materials and additives which are present on the positive list of the current Legislation, comply with the requirements of composition and purity established for the food contact as much are foreseen migration test and respect the specific limits applicable if necessary (Title II capo IV art. 27 comma 1a DM 21/03/1973)., D.M. 18.6.79, Decree 220 26.04.93, D.M. 267 30.05.01 and subsequent updates.

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, 1.2, 1.3, 1.4, 1.5 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, 1.2, 1.3, 1.4 and 1.5 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 products described at point 1.1) paper coated on the inner side with PE film, 1.2 letter j), l); 1.4, based on our declarations suppliers; do not contain monomers and / or additives with specific migration limits.

For products 1.1 letters f) and g): E CUP line the following substances subject to specific migrations are present: 1,4-butanediol (CAS 000110-63-4) with SML (T) 5 mg / kg expressed as 1,4-butanediol; glycidyl methacrylate (CAS 000106-91-2) with SML 0.02 mg / kg (note 10, table 3 of Annex 1-Reg.10 / 2011); methyl methacrylate (CAS 000080-62-6) with SML (T) 6 mg / kg expressed as methacrylic acid; terephthalic acid (CAS 000100-21-0) with SML (T) 7.5 mg / kg expressed as terephthalic acid; from the product (unintentionally added) - tetrahydrofurane (CAS 000109-99-9) with SML 0.6 mg / kg. Hexamethylene diisocyanate (CAS 000822-06-0) SML (T) = N.D.(1 mg/kg in final product expressed as isocyanate moiety). 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 materials referred to in point 1.1 letter e) Paper film for ice cream cups, the following substances subject to specific migrations are present: Acetic acid, vinyl ester (CAS 000108-05-4) SML (T) 12 mg/kg; Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionate (CAS 0002082-79-3) SML (T) 6 mg/kg; 1-octene (CAS 000111-66-0) SML (T) 15 mg/kg; Methacrylic acid (CAS 0000079-41-4) SML (T) 6 mg/kg; Acrylic acid, n-butyl ester (CAS 0000141-32-2) SML (T) 6 mg/kg; Maleic anhydride (CAS 0000108-31-6) SML (T) 30 mg/kg; Caprolactam (CAS 0000105-60-2) SML (T) 15 mg/kg; Terephthalic acid (CAS 0000100-21-0) SML (T) 7.5 mg/kg; Isophthalic acid (CAS 0000121-91-5) SML (T) 5.0 mg/kg;

Hexamethylenediamine (CAS 0000124-09-4) SML (T) 2.4 mg/kg; 2,6-di-tert-butyl-p-cresol (CAS 0000128-37-0) SML (T) 3 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 materials referred to in point 1.2 letter i) the following substances subject to specific migrations are present:

Zinc stearate RN 557-05-1-CAS PM Ref. 89040 - SML = 5 mg / kg for Zn); 1,3-butadieneene CAS 106-99-0 PM Ref. 13630 - SML = not detectable in food; Octadecyl 3- (3,5-di-tert-butyl-4-hydroxyphenyl) ethyl propionate - SML 6mg / kg; 2,4-Bis (dodecylthiomethyl) -6-methylphenol - SML - 5 mg / kg; 2-ethylhexanol - SML - 30 mg / kg; Tris (nonylophenyl) phosphide, phosphoric acid, tris (nonylphenol), ester - SML - 30 mg / kg. Crotonic acid (CAS 0003724-65-0) Ref:14800 SML 0.05 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 materials referred to in point 1.2 letter l<sup>3</sup>) E-CUP line the following substances subject to specific migrations are present:

1,4 butanediol; Glicilmetacrilato; methyl methacrylate; Terephthalic acid; 1,1,1 trimethylolpropane; Unintentionally added substance that can form as a decomposition product of tetrahydrofuran

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 materials referred to in point 1.2 letter k)<sup>1</sup> The following substances subject to specific migrations are present:

Monomer / Additive	PM Rif	Cas n°	SML (mg/Kg)
Isophthalic acid	19150	0000121-91-5	5 (expressed as Isophthalic acid)
Terephthalic acid	24910	0000100-21-0	7,5(expressed as Terephthalic acid)
Ethylene glycol	16990-53650	0000107-21-1	Σ = 30
Diethylene glycol	13326-15760-47680	0000111-46-6	
Antimony trioxide	35760	0001309-64-4	0,004 (expressed as Antimony)
Acetaldehyde	110060	0000075-07-0	6
Etilenglicolmonoalchilettere	77708	-	1,8

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 materials referred to in point 1.2 letter k)<sup>2</sup> the following substances subject to specific migrations are present:

<sup>1</sup> CGC.M2.M3.CS, COP.M2.M3, COP.10MG.20C, COP.M8.B.CS

<sup>2</sup> COP.MD4.G.CS, COP.M4.M500.M70.G.CS, COP.M75.M90.B45.G.CS CGC.MD4.G.CS, CGC.M4.M500.M70.G.CS, CGC.108C.G.CS,

Zinc stearate RN 557-05-1-CAS PM Ref. 89040 - SML = 5 mg / kg for Zn); 1,3-butadienes CAS 106-99-0 PM Ref. 13630 - SML = not detectable in food; Octadecyl 3- (3,5-di-tert-butyl-4-hydroxyphenyl) ethyl propionate - SML 6mg / kg; 2,4-Bis (dodecylthiomethyl) -6-methylphenol - SML - 5 mg / kg; 2-ethylhexanol - SML - 30 mg / kg; Tris (nonylophenyl) phosphite, phosphoric acid, tris (nonylphenol). Antimony trioxide (CAS 0001309-64-4) SML = 0.04 mg/kg; Terephthalic acid (CAS 0000100-21-0) SML=7.5 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 materials referred to in point 1.2 letter k) in PLA the following substances subject to specific migrations are present: Polyethyleneglycol (FCM 799; CAS: X; PM REF. 77708) SML 1.8 mg/kg; Acrylic acid (FCM 147; CAS 0000079-10-7; PM REF. 10690) SML 6 mg/kg; Methacrylic acid (FCM 150; CAS 0000079-41-4; PM REF. 20050) SML 6 mg/kg; Allyl methacrylate (FCM 175; CAS 0000096-05-9; PM REF. 20050) SML 0.05 mg/kg; Dodecylbenzenesulphonic acid (CAS 0027176-87-0; PM REF. 52000) SML 30 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 materials referred to in point 1.3 letter m<sup>1</sup>) The following substances subject to specific migrations are present:

CAS	Sostanza	LMS
13463-67-7	Titanium dioxide, used in polymeric matrix (white PS barch master). The product meets the criteria of purity	There are no SML
100-42-5	Styrene	There are no SML
00016-99-0	Butadiene	QM= 1 mg/kg SML= not analytically determinable
002082-79-3	3- (3,5 - Di-tert-butyl-4-hydroxyphenyl) proparate octadecyl	SML= 6 mg/Kg
36443-68-2	Triethylene glycol-bis [3- (3-ter-butyl-4hydroxy-5methylphenols) propionate)	SML= 9 mg/Kg
557-05-1	Zinc stearate	LMS= 5 mg/Kg as Zn (annex II Reg. 10/11/UE)

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 1.3 lettera m<sup>2</sup>) are present:

CAS	PM Ref	Sostanza	Max contenuto nel film
=	39090	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine	SML=1.2 Max cont. 0.3
0002082-79-3	68320	Octadecyl3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML=6.0 Max cont. 1.4
10094-45-8	68400	Octadecyl erucamide	SML=5 Max cont. < 1
26741-53-7	38820	Bis(2,4-di-ter-butylphenyl) pentaerythitol diphosphate	SML=0.6 Max cont. < 0.1
182121-12-6	39815	9,9-Bis-8methoxymethyl)-9H-fluorene	SML=0.05

			Max cont. <0.02
27676-62-6	95360	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine 2,4,6(1H,3H,5H)-trione	SML=5.0 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).

The products described at point 1.5 comply with the limits of specific migration and specific restrictions in the following test conditions with simulating liquid:

Simulant B)	Acetic acid at 3% (p/v)	at 40°C for 2 hours
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### 7. Compliance with Regulation EC 1333/2008 “Dual Use Additives”

The materials referred to in point 1.1 letters a), b), c), d), g), f) e h) ; 1.2 letters i), j), k), and l); 1.3 letter m<sup>1</sup>); 1.4 e 1.5, based on our declarations suppliers; do not contain substances authorized as as “dual use additives”.

In the materials referred to in point 1.1 letter d) are present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): 3,5-di-tert-butyl-4- hydroxytoluene (E321); Calcium distearate (E470a). However, assuming a 100% migration from the 50my movie will not exceed the food guard level.

In the materials referred to in point 1.2 letter k<sup>1</sup>) are present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): Silicon dioxide (PM Rif. 86240, E 551), Phosphoric acid (PM Rif. 23170-72640, e 338), Sorbic acid (PM Rif. 87200, E 200), Polydimethylsiloxane (PM Rif. 76721, e 900).

In the materials referred to in point 1.2 letter k) PLA are present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): Lactic acid (E270) (FCM 99; CAS 0000050-21-5; PM REF. 19460 62960); Sorbic acid (FCM 252; CAS 0000110-44-1; PM REF. 87200); Polydimethylsiloxane (MW > 6 800 DA) (FCM 575; CAS 0063148-62-9; PM REF. 76721).

In the materials referred to in point 1.2 letter l<sup>3</sup>) E-CUP line are present “dual use” substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): titanium dioxide and talc. In the EC Regulation 10/2011 there are no restrictions for the substances contained.

In the materials referred to in point 1.3 letter m<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
E559	Aluminium silicate (Kaolin)

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

With reference to the products referred to in points 1.1, 1.2, 1.3, 1.4 and 1.5 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 points 1.1, 1.2 and 1.3 do not contain epoxy derivatives

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

The products referred to points 1.1, 1.2 letter l) PLA, 1.4 and 1.5, 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 and 1.2 are intended to come into contact with food products as classified under Regulation EC 10/2011 (ref. Table 2 Annex III): beverages, cereals and derived products in the bakery wares, chocolate and sweets, fruits vegetables and dairy products, fats and oils, animal products and eggs, dairy products, various products (fried or roasted foods, soups, sauces, sandwiches, ice cream, frozen foods, cacao, coffee, spices).

The products referred to point 1.3 are intended to come into contact with food products as classified under Regulation EC 10/2011 (ref. Table 2 Annex III): ice cream.

The products referred to point 1.4 are intended to come into contact with cereals and derived products in the bakery wares.

The products referred to point 1.5 are intended to come into contact with foods whose matrix can be watery, oily, acidic, alcoholic.

### 12. Suitability for use

The products referred to paragraph 1.1, 1.2 are:

- suitable to be used at high temperature together with the food product for 2 hour, at 70° degree temperature,
- 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,
- suitable for microwave,
- not suitable for use in a traditional oven together with the food product;

Note: if used to keep frozen products the cups mentioned in point 1.1 absorb humidity at room temperature.

The products referred to paragraph 1.3 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.

The products referred to paragraph 1.4 are:

- suitable to be used together with the food product for 2 hours, at 25°-degree temperature,
- not suitable for use in a traditional oven together with the food product.

The products referred to in points 1.5 are:

- suitable for use in combination with solid, hot and cold food products at 80 ° C use conditions.

### 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. Compliance with Regulation EU MID 32/2014

The products used like measure capacity, referred to point 1.1 letters a), b), are disposable and measures volume is calculated at 20 degrees.

#### 16. 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)