

To: **EISUNION GMBH**

Salerno, 08.07.2026

Object: Medac Product declaration of conformity

Medac s.r.l., located in Robert Wenner 52 Street, in Salerno, , hereby declares 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) Chips paper cups,
- d) Pop Corn paper cups
- e) Paper discs,
- f) Paper seals for ice cream cups,
- g) Cardboard lids,
- h) Ice cream paper cups,
- i) Food paper cups,
- j) Food paper box,
- k) Flower paper cups

1.2 Plastic products

- l) Plastic Lids for drinking paper cups,
- m) Plastic Lids for hot drinking paper cups,
- n) Flat and Cupolini Plastic Lids for Paper Ice Cream Cups,

1.3 Plastic products

- o) Polystyrene boxes,
- p) Films for polystyrene boxes

1.4 Paper products

- q) Paper sleeves

1.5 Wood products

- r) 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 EU 10/2011 and amendments (latest Regulation EU 2025/351),
- Regulation (EU) 2024/3190, as amended by Regulation (EU) 2026/250,
- Regulation EC 2023/2006,
- Regulation EC 1895/2005,
- Directive (EU) 2018/852 of 30 May 2018 (amending Directive 94/62/EC Regulation)
- EC 1935/2004 Article 3, Article 11 paragraph 5, Article 15 and Article 17,
- D.M. 21/03/1973 and its amendments,
- Regulation (EU) 2025/40.



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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,
- Directive (EU) 2018/852 of 30 May 2018 (amending Directive 94/62/EC Regulation),
- Regulation (EU) 2025/40.

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,
- DPR 777/82,
- Regulation EC 1907/2006/ (REACH),
- Regulation (EU) 2025/40.

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 a), b), f), g), h): E CUP line, multilayer paper of virgin cellulose coated on the inner side with biodegradable film. No use of recycled material.

The printing inks are low migration, produced according to the "EUPIA Guidelines on printing inks applied to the non-food contact surface of food packaging materials and articles" and "CEPE-EUPIA Good Manufacturing Practices for the production of inks for food packaging. The inks also comply with the Swiss ordinance edi 817.023.21.

For the products mentioned in point 1.2:

- letter l) Polystyrene,
- letter m) Polystyrene,
- letter n) PET

For the products mentioned in point 1.3:

- letter o¹) Polistirene (plastic membrane)
- letter o²) EPS (Box and Lid)
- letter p) Polypropylene (Film)

For the products mentioned in point 1.4:

natural paper from 100% virgin fiber

The printing inks are low migration, produced according to the "EUPIA Guidelines on printing inks applied to the non-food contact surface of food packaging materials and articles" and "CEPE-EUPIA Good Manufacturing Practices for the production of inks for food packaging. The inks also comply with the Swiss ordinance edi 817.023.21.

For the products mentioned in point 1.5:

natural birch wood, without treatments

4. Compliance with migration limits



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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
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 paragraph 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 restrictions placed 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, 1.5 don't 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, 1.5 don't 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 dm² per kg of foodstuff.

5. Compliance with SML

The materials referred to in the products referred to in points 1.1) multilayer of pure virgin fiber paper with PE film coating, letters a) drinking paper cups, c) chip paper cups, d) popcorn paper cups, e) Paper discs, , i) food paper cups, j) food paper box, k) flower paper cups; 1.5 based on the declarations of our suppliers, do not contain monomers and/or additives for which specific migration limits are regulated.

The inks and varnishes are applied on the non-food-contact side and have been assessed as suitable for the intended use; therefore, they do not fall within the materials for which the indication of specific migration limits (SML) is required.

In materials used in the extrusion coating of the products referred to in point 1.1 letters b), h) are present substances used in the extrusion coating listed in Annex II according to Commission Regulation (EU) 10/2011 as amended:

Substance	Specific migration limit, SML (mg/kg food)	Maximum concentration (mg/kg food)
Aluminium	1	0,01
Antimony	0,04	0,0007



Arsenic	ND	0,005
Barium	1	0,002
Cadmium	ND (LOD 0,002)	2e-06
Chromium	ND	0,002
Cobalt	0,05	0,0007
Copper	5	0,005
Europium	0,05	4e-08
Ganolidium	0,05	4e-08
Iron	48	0,01
Lanthanum	0,05	0,00000004
Lead	ND	0,008
Lithium	0,6	0,006
Manganese	0,6	0,005
Mercury	ND	6e-05
Nickel	0,02	1e-05
Terbium	0,05	4e-08
Zinc	5	0,02

For products 1.1 letters a), b), g), and h): 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; terephthalic acid (CAS 000100-21-0) with SML (T) 7.5 mg / kg expressed as terephthalic acid; from the product (unintentionally added) - tetrahydrofuran (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 f) Paper seals for ice cream cups E CUP line, the following substances subject to specific migrations are present: Hexamethylenediisocyanate (FCM-No. 372) SML (T) N.D. (1mg/kg in the final product, expressed as isocyanate moiety); 1,4-Butanediol (FCM-No. 254) SML (T) 5 mg/kg; Terephthalic acid (FCM-No. 785) SML (T) 7.5 mg/kg; Tetrahydrofuran (FCM-No. 246)) SML 0.6 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 1.1 letter f) Paper seals for ice cream cups, the following substances subject to specific migrations can be present: Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate (CAS :2082-

79-3) 6 mg/kg ; Octene (Ref. No : 22660, CAS : 111-66-0) = 15 mg/kg; Acetic acid, vinyl ester (FCM : 231, CAS : 108-05-4) = 12 mg/kg; Acrylic acid, n-butyl ester [PM ref.: 10780]=6 mg/kg; Maleic anhydride [PM ref.: 1996030]= 30mg/kg (expressed as maleic acid); Caprolactam (Ref. No. 14200, CAS No. 105-60-2): 15 mg/kg; Terephthalic acid (Ref. No. 24910, CAS No. 100-21-0): 7.5 mg/kg; Isophthalic acid (Ref. No. 19150, CAS No. 121-91-5): 5.0 mg/kg; Hexamethylenediamine (Ref. No. 18460, CAS No. 124-09-4): 2.4 mg/kg; 2,6-di-tert-butyl-p-cresol (CAS No 128-37-0): 3mg/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 1.1 letter g) cardboard lids, the following substances subject to specific migrations are present:

264 111-66-0 1-Octene EU: SML = 15 mg/kg

* 356 592-41-6 1-Hexene EU: SML = 3 mg/kg

*223 106-99-0 Butadiene EU: max. 1 mg/kg of the material or article or SML = ND

294 123-28-4 Propanoic acid, 3,3'-thiobis-, didodecyl ester EU: SML(T) = 5 mg/kg

Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate EU: SML = 6 mg/kg

Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks DUA: E 905

The materials referred to in point 1.2) plastic lids for drinking paper cups the following substances subject to specific migrations are present: "Butadiene, CAS No 106-99-0, SML = not detectable, Styrene, CAS No 100-42-5, SML < 60mg/kg, Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl) propionate, CAS No. 2082-79-3, SML = 6mg/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) plastic lids for hot drinking paper cups (CBC.237CK, CBC.30.45.58CK) the following substances subject to specific migrations are present: Triethyleneglycol bis[3-(3-tert- butyl-4-hydroxy-5- methylphenyl) propionate] (CAS 0036443-68-2) SML 9 mg/kg; Stearic acid (CAS 0000057-11-4) SML 5 mg/kg; Zinc SML 5 mg/kg; Butadiene (CAS 0000106-99-0) SML ND; Acrylic acid, 2,4-di-tert-pentyl-6- (1-(3,5-di-tert-pentyl-2- hydroxyphenyl)ethyl)phenyl ester (CAS 0123968-25-2) SML 5 mg/kg; Lithium 6 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) plastic lids for hot drinking paper cups (CBC.10CK, CBC.118CK) the following substances subject to specific migrations are present: "Butadiene, CAS No 106-99-0, SML = not detectable, Styrene, CAS No 100-42-5, SML < 60mg/kg, Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl) propionate, CAS No. 2082-79-3, SML = 6mg/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).

In the materials referred to in point 1.2)¹ Flat and Cupolini Plastic Lids for Paper Ice Cream Cups, 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
Etilenglicolmonoalchilitere	77708	-	1,8

¹ CGC.M2.M3.CS, CGC.10MG.20C.CS1
COP.M2.M3, COP.10MG.20C COP.M7.B64.B.CS COP.M8.B.CS



In the materials referred to in point 1.2 letter o) flexible lids for ice cream cups (COP.B99) the following substances subject to specific migrations are present: Butadiene (CAS 000000106-99-0) SML (mg/kg) 0.01; Propionate of octadecyl (CAS 0002082-79-3) SML (mg/kg) 6.

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).

In the materials referred to in point 1.2) Flat and Cupolini Plastic Lids, 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-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 (nonyl phenyl) 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 1.3 letter o¹) Plastic membrane (Polystyrene) the following substances subject to specific migrations are present:

CAS	Substances	LMS
013463-67-7	Titanium dioxide, in polymer matrix (PS master batch white) Meets purity criteria	No SML.
000100-42-5	Styrene	No SML.
000106-99-0	Butadiene	QM=1 mg/kg SML= inferiore a LR
002082-79-3	3-(3,5 Di-tert-butyl-4-hydroxyphenyl) octadecyl propionate	SML= 6mg/kg
036443-68-2	Triethylene glycol-bis (3-tert-butyl-4-hydroxy-5-methylphenyl)propionate)	SML= 9mg/kg
000557-05-1	Zinc stearate	SML= 5mg/kg Zn (annex II Reg. 10/11 EU)
106-99-0	1,3 butadiene	QM 1mg/kg
91051-01-3/557-05-1	Zinc, Salts from fatty acids (C16 – C18)	0,83 mg/dm2 come Zn
2082-79-3	Octadecyl-3-(3,5 di tert-butyl-4-hydroxyphenyl)propionate	1mg/dm2
110553-27-0	2,4-bis-(octylthiomethyl)-6-methylphenol	0,83 mg/dm2
26523-78-4	Tris(nonylphenyl)phosphite	5mg/dm2
36443-68-2	Triethylene glycol-bis[3-(3-tert butyl-4-hydroxymethyl phenyl) propionate]	1,5 mg/dm2
38613-77-3	Tetrakis-(2,4-ditertbutyl-phenyl)-4,4-biphenylenediphosphonite	3mg/dm2

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).

² COP.B32.G.CS, COP.B32.G.CS.TC, COP.MD4.G.CS, COP.M4.M500.M70.G.CS, COP.M75.M90.B45.G.CS COP.16G.CS CGC.MD4.G.CS, CGC.M4.M500.M70.G.CS, CGC.108C.G.CS, CGC.16B.9C.G.CS, CGC.4C.5M.7C.G.CS



The materials referred to in point 1.3 letter o²) box and lid, the following substances subject to specific migrations are present:

CAS	Substances	SML
FCM-No: 16	Butadiene	6 mg/kg
	Zinc salt	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 1.3 letter p) film (polypropylene) are present:

CAS	PM Ref	Substances	Max contained in the film
0061791-44-4	39090	N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	SML=1.2 Max cont. 0.81
0002082-79-3	68320	3-(3,5-di-tert-butyl-4-hydroxyphenyl) octadecyl propionate	SML=6.0 Max cont. 0.0022
0119345-01-6	83595	Reaction product of di-tert-butyl-diphenyl phosphite	SML=18 Max cont. 0.0162
26741-53-7	38820	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML=0.60 Max cont. 0.0162
182121-12-6	39815	9,9-bis(methoxymethyl)fluorene	SML=0.05 Max cont. 0.0324
27676-62-6	95360	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazin- 2,4,6(1H,3H,5H)-trione	SML=5.0 Max cont. 0.0005
0000080-62-6	21130	Methacrylic acid, methyl ester	SML=6 Max cont. 0.0005
0000106-91-2	20590	2,3-epoxypropyl ethacrylate	SML=0.02 Max cont. 0.0005
0007429-90-5	--	Aluminium	SML=1.00 Max cont. 0.1620

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 1.4), the following substances subject to specific migrations are present:

264 111-66-0 1-Octene EU: SML = 15 mg/kg

* 356 592-41-6 1-Hexene EU: SML = 3 mg/kg

*223 106-99-0 Butadien EU: max. 1 mg/kg of the material or article or SML = ND

294 123-28-4 Propanoic acid, 3,3'-thiobis-, didodecyl ester EU: SML(T) = 5 mg/k

Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate EU: SML = 6 mg/kg

Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks DUA: E 905

6. Use/Non-use of food additives “Dual Use Additives” and flavourings

The materials referred to in point 1.2) plastic lids for drinking paper cups, m) plastic lids for hot drinking paper cups (CBC.118CK; CBC.10CK; Flat and Cupolini Plastic Lids (COP.B32.G.CS, COP.B32.G.CS.TC, COP.MD4.G.CS, COP.M4.M500.M70.G.CS, COP.M75.M90.B45.G.CS COP.16G.CS, COP.B99.CS, COP.M75.M90.B45.D.CS, CGC.MD4.G.CS, CGC.M4.M500.M70.G.CS, CGC.108C.G.CS, CGC.16B.9C.G.CS, CGC.4C.5M.7C.G.CS); 1.4, 1.5, based on our declarations suppliers do not contain food additives authorized as “dual use additives” (Regulation EC 1333/2008), flavorings or food ingredients with flavoring characteristics (Regulation EC 1334/2008).



The inks and varnishes are applied on the non-food-contact side and have been assessed as suitable for the intended use; therefore, they do not fall within the materials for which the indication of dual-use additives is required.

In the materials referred the products referred to point 1.1 letter b) hot drinking paper cups can be present “dual use” substances (ex EC Reg. 1333/2008 - EC Reg. 1334/2008):

Chemical substance	CAS-number	E number/FL number
Polyethylene glycol	25322-68-3	E1521
Sodium bisulfite	7631-90-5	E222
Sodium nitrate	7631-99-4 E251	E251
Citric acid	77-92-9	E330
Adipic acid	124-04-9	E355
Sorbitan monolatte	1338-39-2	E493
Sodium carbonate	207-838-8	E500
Magnesium chloride	7786-30-3	E511
Sulfuric acid	7664-93-9	E513
Sodium sulfate	7757-82-6	E514
Ammonium sulfate	7783-20-2	E517
Aluminum sulfate	10043-01-3	E520
Sodium hydroxide	1310-73-2	E524
Silicon dioxide	112926-00-8	E551
Silicon dioxide	7631-86-9	E551
Stearic acid	57-11-4	E570
Calcium carbonate	471-34-1	E170
Urea	57-13-6	E927B
Naphthalenesulfonic acid polymer associato a E524	9084-06-4	E524

In the materials referred the products referred to point 1.1 letter h) ice cream paper cups can be present “dual use” substances (ex EC Reg. 1333/2008 - EC Reg. 1334/2008):

Chemical substance	CAS-number	E number/FL number
Adipic acid	124-04-9	E355
Ammonium hydroxide	1336-21-6	E527
Ammonium sulphate	7783-20-2	E517
Calcium carbonate	471-34-1	E170
Citric acid	77-92-9	E330
Fatty acids C16-18, calcium salts	85251-71-4	E470a
Glycerol	56-81-5	E422
Maleican hydride	108-31-6	E296
Polyethylene glycol	25322-68-3	E1521
Silicon dioxide	12926-00-8; 7631-86-9	E551
Sodium acetate	127-09-3	E262
Sodium hydroxide	1310-73-2	E524
Sodium metabisulphite	7681-57-4	E223



Sodium nitrate	7631-99-4	E251
Sodium sulfate	7757-82-6	E514
Sodium sulphite	7631-90-5	E221
Sorbitan laurate	1338-39-2	E493
Sorbitan monostearate	1338-41-6	E491
Sulfuric acid, aluminum salt (3:2), tetradecahydrate	16828-12-9	E520
Sorbitol Sodium bicarbonate	50-70-4.	(E420),
Sorbitol Sodium bicarbonate	144-55-8	(E500)

In the materials referred to point 1.1) Multilayer paper of virgin cellulose coated on the inner side with PE film letters a) drinking paper cups, c) chips paper cups, d) popcorn paper cups, e) paper discs, g) cardboard lids, i) food paper cups, J) food paper box, k) flower paper cups; 1.1 letters a), b), f), g), h) (E-CUP line) can be present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): calcium carbonate (E170), sorbitol (E420), sodium bicarbonate (E500)

In the materials referred to point 1.1 letter f) paper seals, can be present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): 3,5-di-tert-butyl-4- hydroxytoluene (E321).

In the materials referred to in point 1.2) plastic lids for hot drinking paper cups (CBC.237CK; CBC.30.45.58CK) can be present "dual use" substances (ex Reg. CE 1333/2008 - Reg. CE 1334/2008): Titanium dioxide (CAS:13463-67-7).

In the materials referred to in point 1.2 o³) Flat and Cupolini Plastic Lids, can be 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 constituting the products referred to in point 1.3. o¹) plastic membrane (Polystyrene), can be present "dual use" substances (ex Reg. EC 1333/2008 - Reg. EC 1334/2008) compliant with EU regulation.10/2011 and subsequent updates: Titanium dioxide (E 171), Calcium salt of fatty acids (C16-C18) E470a.

In the materials referred to in point 1.3 o²) box and lid (EPS) can be present substances "dual use" (ex Reg. CE 1333/2008 - Reg. CE 1334/2008) in compliance with the regulation EU.10 / 2011 and subsequent updates: Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono- and triglyceride esters (FCM-No: 10).

In the materials referred to in point 1.3 letter p) film (Polypropylene) can be 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	Synthetic silica
E 470b	Magnesium stearate
E470a	Calcium salts of fatty acids

³ CGC.M2.M3.CS, CGC.10MG.20C.CS1
COP.M2.M3, COP.10MG.20C COP.M7.B64.B.CS, COP.M8.B.CS



7. Compliance with NIAS (Not intentionally added substances)

With reference to the products referred to in points 1.1, 1.2, 1.3, 1.4, 1.5 regarding the NIAS, if present, a risk assessment was conducted in accordance with art. 19 of the Regulation / UE and of the art. 3 of Regulation 1935/2004 / EC.

With reference to the organoleptic requirements set out in Article 3 of Regulation (EC) No. 1935/2004, the products covered by this declaration are subjected to sensory testing intended to verify the absence of any adverse organoleptic effects on food. Such testing is carried out in accordance with UNI 10192:2000 – Method C and UNI 10192:2000 – Method F. The results of the tests confirm that, under the intended and declared conditions of use, the products do not transfer abnormal odours and/or flavours to food.

8. Compliance with Regulation EC 1895/2005

The products referred to points 1.1, 1.2, 1.3 do not contain epoxy derivatives.

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

The products referred to points 1.1, 1.2, 1.3, 1.4, 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.

10. 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, and alcoholic.

11. 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 hours, at 70°-degree temperature = 100 °C gr max $t = 120/2^{(T-70)/10}$ minutes,
- suitable to be stored at low temperature together with the food product for a period longer than 1 month, 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 a period longer than 1 month, 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.

12. 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.

13. 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.

The technological suitability of the product, whereby such suitability is understood as the functional adequacy for the specific intended use (including, but not limited to, filling methods, temperature, contact time, and packaging and automation systems), shall be assessed and validated by the customer/final user, in accordance with Article 3 of Regulation (EC) No. 1935/2004.

14. 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.

15. Compliance with Article 5 of Regulation (EU) 2025/40 (PPWR)

Based on the analytical test results obtained, the products referred to point 1.1, 1.2, 1.3, 1.4, 1.5 comply with the requirements of Article 5 of Regulation (EU) 2025/40 concerning the content of PFAS and heavy metals, and in particular with the following limits:

- Individual PFAS ≤ 25 ppb;
- Sum of PFAS ≤ 250 ppb;
- Total PFAS (including polymeric PFAS) ≤ 50 ppm;
- Sum of heavy metals (Pb, Cd, Hg and Cr VI) < 100 mg/kg.

It is further declared that substances belonging to the PFAS family are not intentionally added either during the formulation of the raw materials or during the manufacturing process.

Based on the available analytical evidence and the information provided by the raw material suppliers, the product complies with the applicable requirements of Article 5 of Regulation (EU) 2025/40.

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
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