Industrial Park, 9704 Shumen, Bulgaria
Tel.: +359 54 974 166
WEB: www.artemis.bg

DECLARATION OF CONFORMITY

The undersigned ARTEMIS LTD,
Address: Industrial Park, Third street, Building 2, 9704 Shumen,Bulgaria
Tel : (+359) 54 974 166

declares under our own responsibility, that the following products: **Plastic bag type "Bag in Box",** different volumes, for filling food and beverage, beverages alcoholics 20°, juices, oil, eggs, milk and dairy products, not irradiated,

Are produced in compliance with the regulations:

- ORDINANCE № 2 of 23.01.2008, amendment in Public Newspaper edition 72 of 16.08.2013, relating to plastic materials and articles intended for food contact.

- ORDINANCE № 4 from25.06.1999 for withdrawal and destruction of dangerous goods.

- ORDINANCE № 1 from26.01.2016 for the food hygiene, last amendment Ordinance No14 from 09.12.2021

- Food Law of 15.10.1999, amendment of 09.06.2020.

- Regulation (EC) № 1935/2004 art. 1 of the European Parliament and of the Council of 27 October 2004. Concerning the materials and articles intended for contact with food and repealing Directives 80/590 / EEC and 89/109 / EEC and last amendment on 27.03.2021.

- Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. Last amendment 17.04.2008.

- Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, last amendment on 04.07.2018

- Commission Regulation (EU) No 10/2011 on Plastic Materials and Articles Intended To Come Into Contact With Food and relevant amendments and its amendments. Last amendment 23.09.2020

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Overall Migration

All products described above, supplied by Artemis Ltd, comply with current legislation. The Overall Migration Limit defined in the directives is 10 mg/dm² (60mg/kg). The chosen test conditions are according to the requirements of Regulation (EU) No 10/2011 for all type of foods.

Results from last tested bags MetPet with PE, BIB

Simulant	Conditions	Test result, mg/dm²	Limit, mg/kg
B-3 % acid	10 days, 40°C	<5.0	60
C-20 % ethanol	10 days, 40°C	<5.0	60
D-95% ethanol	10 days, 40°C	<5.0	60

Results from last tested bags EVOH with PE, BIB

Simulant	Conditions	Test result, mg/dm²	Limit, mg/kg
B-3 % acid	10 days, 40°C	<5.0	60
C-20 % ethanol	10 days, 40°C	<5.0	60
D-95% ethanol	10 days, 40°C	<5.0	60

Overall migration for the used films:

Results from last tested Metalized film

Simulant	Conditions	Test result, mg/dm²	Limit, mg/dm²
B-3 % acid	10 days, 60°C	<1	10
C-20 % ethanol	10 days, 60°C	<1	10
95% ethanol	10 days, 60°C	<1	10

Results from last tested PE/EVOH/PE-transparent film

Simulant	Conditions	Test result, mg/dm²	Limit, mg/dm²
B-3 % acid	10 days, 60°C	<1	10
C-20 % ethanol	10 days, 60°C	<1	10
95% ethanol	10 days, 60°C	<1	10

Results from last tested (LLDPE and LDPE)-transparent film

Simulant	Conditions	Test result, mg/dm²	Limit, mg/dm²
B-3 % acid	10 days, 60°C	<1	10
C-20 % ethanol	10 days, 60°C	<1	10
95% ethanol	10 days, 60°C	<1	10
D2-olive oil	10 days, 60°C	<2	10

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Substances, with restrictions imposed by Regulation (EU) No 10/2011, are in following Tables.

SML for the used raw materials on the base of supplier declaration and documents:

Poly Laminated Metalized film

Cas No	Monomer	Simulant	Conditions	Test results	SML, mg/kg
0000074-85-1	ethylene				-
0000111-66-0	1-octene	Olive oil	60°, 10days	<15 mg/kg	15
0000112-84-5	erucamide				-
0000301-02-0	oleamide				-
0000592-41-6	1-hexene	Olive oil	60°, 10days	<3000µg/kg	3
0007631-86-9	Silicon dioxide				-
0000064-17-5	Ethanol				-
0000141-78-6	Ethyl Acetate				-
	Aluminum powder				-
0007631-86-9	Silicon dioxide				-
0013463-67-7	Titanium dioxide				-
0000107-21-1	Ethylene glycol				-
0000100-21-0	Terephthalic acid				-
0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-				6
	Zinc Stearate Ref. Nr 89040				-

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Film PE/EVOH/PE-transparent

Cas No	Monomer	Simulant	Conditions	Test results	SML, mg/kg
0000074-85-1	ethylene				-
0000111-66-0	1-octene	Olive oil	60°, 10days	<15 mg/kg	15
0000112-84-5	erucamide				-
0000301-02-0	oleamide				-
0000592-41-6	1-hexene	Olive oil	60°, 10days	<3000µg/kg	3
0007631-86-9	Silicon dioxide				-
0000108-05-4	acetic acid, vinyl ester	95% ethanol	60°, 10days	<12 mg/kg	12

Polyethylene film (LLDPE and LDPE)-transparent

Cas No	Monomer	Simulant	Conditions	Test results	SML, mg/kg
0000074-85-1	ethylene				-
0000111-66-0	1-octene	Olive oil	60°, 10days	<15 mg/kg	15
0000112-84-5	erucamide				-
0000301-02-0	oleamide				-
0000592-41-6	1-hexene	Olive oil	60°, 10days	<3000µg/kg	3
0007631-86-9	Silicon dioxide				-
0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-				6
	Zinc Stearate Ref. Nr 89040				-

Blue masterbatch:

Cas No	Monomer	Simulant	Conditions	Test results	SML, mg/kg
0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-				6
	Zinc				5

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Vitop Tap:

Substance	CAS-Nr.	SML, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6
1,4 Butanediol	110-63-4	5
Tetrahydrofuran	109-99-9	0,6
2,6-di-tert-butyl-p-cresol	128-37-0	3
Zinc		5

I-tap tap:

Substance	Ref Nr.	SML, mg/kg
Glycerides, Castor Oil mono-hydrogenates, Acetates	55910	-
9,9-bis(methoxymethyl)fluorine	39815	0,05
Tetrahydrofuran	25150	0,6
1,4 butanediol	13720	-
Green Masterbatch: Octadecil 3-(3,5-di-tert-butil-4-idrossifenil) propinato	68320	6
Green Masterbatch: Alkyl(C8-C22) sulphonic acid	34230	6
Green Masterbatch: Zinc Stearate	89040	-
Green Masterbatch: Aluminum		
Green Masterbatch: Copper		
Orange Masterbatch: Aluminum		
Red Masterbatch: Iron		
Red Masterbatch: Barium		
Blue Masterbatch: Copper		
Blue Masterbatch: Aluminum		

I-tap gland

Substance	CAS-Nr.	SML, mg/kg
Octadecil 3-(3,5-di-tert-butil-4-idrossifenil) propinato	68320	6
Aluminium	-	1

Vitop gland:

Substance	CAS-Nr.	SML, mg/kg
Octadecyl 3-(3,5-i-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6
Stearic acid–expressed as Zinc	57-11-4	5
Iron	-	48
Aluminium	-	1

MH 609/ASM0009

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6

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caprolactam	group restriction table 2 regulation EU No 10/2011	15
annex II (Zn) in combination with zinc ferrite		25

MH1401RH/MLD0078

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6

MH1404/MLD0012

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6

MH1401/MLD0088

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6
annex II Zinc	-	25

MH801HR/MLD013

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6
Octene-1	0111-66-0	15
Phthalsäure, Dibutylester	0084-74-2	0,30
1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethylpiperidin-dimethylsuccinat, Copolymer	65447-77-0	30
Bis(hydriertes Talg-Alkyl)amin, oxidized	43925-92-2	43925-92-2

MH902/MLD008

Substance	Cas Nbr	Restriction, mg/kg
Octene-1	0111-66-0	15

MH608/MLD0085

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6

MH609/screw cap blue

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-	2082-79-3	6

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butyl-4-hydroxyphenyl)propionate		
2,6-Di-tert-butyl-p-kresol (BHT	0128-37-0	3
annex II Copper	-	5

MH4502/MLD0083

Substance	Cas Nbr	Restriction, mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6 mg/kg
annex II Nickel		0,02 mg/kg

MLD032/MH902HR

Substance	CAS-Nr.	Restriction
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6 mg/kg
annex II (Zn) in combination with zinc ferrite	-	5 mg/kg
Octene-1	0111-66-0	15 mg/kg

MLD0069/MH610

Substance	CAS-Nr.	Restriction
caprolactam	group restriction table 2 regulation EU No 10/2011	15 mg/kg
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	6 mg/kg
butadiene	0106-99-0	not-detectable
2,4-bis(octylthiomethyl)-6-methylphenol	110553-27-0	5 mg/kg
acetic acid, vinyl ester	0108-05-4	12 mg/kg
4,4'-thiobis(6-tert-butyl-3-methylphenol)	96-69-5	0,48 mg/kg
3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	65140-91-2	6 mg / kg
annex II Zinc - 5 mg/kg		

Dual use additives:

Information for dual use additive according suppliers statements and documents:

Blue masterbatch

Substance	E number
Calcium carbonate	E170

Vitop tap

Substance	E number
Calciumstearate	E470a

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Vitop gland

Substance	**E number**	% in the raw material	% of use of the raw material in VitopStandard Gland
Silicon dioxide	E551	7%	2,5%
Aluminium	E173		2,5%

I-tap tap

Substance	**Ref. No**
Glycerides, Castor Oil mono-hydrogenates, Acetates 55910	55910
9,9-bis(methoxymethyl)fluorine 39815	39815
Tetrahydrofuran 25150	25150
1,4 butanediol 13720	13720
Green Masterbatch: Octadecil 3-(3,5-di-tert-butil-4-idrossifenil) propinato 68320	68320
Green Masterbatch: Alkyl(C8-C22) sulphonic acid 34230	34230
Green Masterbatch: Zinc Stearate 89040	89040
Green Masterbatch: Aluminum	
Green Masterbatch: Copper	
Orange Masterbatch: Aluminum	
Red Masterbatch: Iron	
Red Masterbatch: Barium	
Blue Masterbatch: Copper	
Blue Masterbatch: Aluminum	

I-tap gland

Substance	**Ref. No**
Octadecil 3-(3,5-di-tert-butil-4-idrossifenil) propinato	68320
Aluminum	

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MH609/ASM0009

Substance	Cas Nbr	E-Nr
Sorbitantristearate	26658-19-5	
Calciumstearate	00057-11-4	

MH1401RH/MLD0078

Substance	Cas Nbr	E-Nr
Non-included		

MH1404/MLD0012

Substance	Cas Nbr	E-Nr
Non-included		

MH1401/MLD0088

Substance	Cas Nbr	E-Nr
Titanium dioxide	13463-67-7	E171

MH801HR/MLD013

Substance	Cas Nbr	E-Nr
Sorbitantristearate	26658-19-5	-
Calciumstearate	00057-11-4	-

MH902/MLD008

Substance	Cas Nbr	E-Nr
Not included	-	-

MH608/MLD0085

Substance	Cas Nbr	E-Nr
Not included	-	-

MH609/screw cap blue

Substance	Cas Nbr	E-Nr
Calciumstearate	-	E470a
Glycerol monostearate	-	E471
Talcum	-	E553b
Titanium dioxide	13463-67-7	E171
Butylhydroxytoluol	-	E321
Calcium carbonate	-	E170

MH801/MLD009

Substance	Cas Nbr	E-Nr
Not included	-	-

MH4501HR/MLD0049

Substance	Cas Nbr	E-Nr
Not included	-	-

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MH4501/MLD0028

Substance	Cas Nbr	E-Nr
Sorbitantristearate	26658-19-5	-
Calciumstearate	00057-11-4	-

MH903HR/MLD033

Substance	Cas Nbr	E-Nr
Sorbitantristearate	26658-19-5	-
Calciumstearate	00057-11-4	-

MH4502/MLD0083

Substance	Cas Nbr	E-Nr
Sorbitantristearate	26658-19-5	-
Calciumstearate	00057-11-4	-

MH4502/MLD0083

Substance	CAS-Nr.	E-Nr.
Sorbitantristearate	26658-19-5	-
Calciumstearate	00057-11-4	-

MLD0069/MH610

Substance	Cas Nbr	E-Nr
Not included		-

Based on declarations of our raw material suppliers and our technology, hereby we declare that no non-intentionally added substances (NIAS) have been added for a technical purpose during production. They include degradation products during production, impurities of raw materials, unwanted side-products and various contaminations from production process. Potential health risks of raw material contaminants; process contaminants and environmental contaminants associated with NIAS are assessed.

Additives which are not regulated in the EU Directives are according to Food and Feed Code (LFGB – BGBI.IS.945 last amended on 26.04.2006). In this regard we have certificates from our plastic suppliers. As we do not add anything to the plastics during the production process, the declaration from our suppliers also applies to our Bag-in-Box packaging. These Directives, Ordinances and legal regulations stipulate the requirements and preconditions in respect of materials and articles intended to come into contact with foodstuffs.

The films used to manufacture the bag are dictated by the barrier requirements of the product carried, and this determines their ability to be recycled. All bags and fitments made from PE can be fully recycled. For the production of BIB are not used any recycled materials. All raw materials used for BIB production are with European origin. No restrictions for use the BIB.

These bags are suitable for filling food products. The food packer is responsible for ensuring that the finished food package complies with applicable migration limits in the food itself under actual conditions of use. Possible interactions of the packaging material and its components with the foodstuffs or pet foods are to be checked prior to use and in function of the end- uses.

Artemis Ltd,
Last revision 08.07.2022

Shoumen, Bulgaria ARTEMIS Ltd Shoumen, Bulgaria