TENCO S.R.L. unipersonale
Via Arbora 1
16030 AVEGNO (GE) Italy
P.IVA / VAT 03111170100

tecnica e tecnologia del confezionamento

tel +39-0185-79.556 r.a.
fax +39-0185-79.412
info@tenco.it
www.tenco.it

DECLARATION OF FOOD COMPLIANCE

We hereby declare that the item provided:

Enolmatic vacuum filler

1 filling spout in polyethylene:	*reference code*	*900-0001-001* *900-0001-002* *900-0001-003* *900-0001-005* *900-0001-006* *900-0001-007* *900-0001-008* *900-0001-009* *900-0001-010* *900-0001-011*
1 filling spout in stainless steel:	*reference code*	*900-0001-004* *900-0001-012* *900-0001-013* *900-0001-104* *900-0001-105* *900-0001-106* *900-0001-108*

General requirements

Complies with the following European Union (EU) legislation:

Regulation (EC) No. 1935/2004 and subsequent updates and changes;
Regulation (EC) No. 2023/2006 and subsequent updates and changes;

Complies with the following Italian legislation:

D. M. 21/03/1973 and subsequent updates and changes;
Presidential Decree 777/82 and subsequent updates and changes;
Legislative Decree n ° 29/2017.

It is specified that the parts in direct / indirect contact are indicated in the technical documentation present in the Company.

Declare that:
For the correct operation of the machine, i
t is necessary that the following logistic and environmental conditions are respected:

- *Place of installation: the machine must be positioned in an environment protected from atmospheric agents. Remember that the machine is equipped with electrical devices; therefore it is recommended to position the machine as far as possible from water inlets and possible sources of splashes.*

- *Room temperature: the mechanical parts and the components of which the machine is composed are suitable to operate in a range of outdoor ambient temperatures ranging from +10 ° C to +40 ° C. Any fluctuations in the ambient temperature from +5 ° C to + 45 ° C are allowed for short periods.*

- *In non-operational conditions the machine must never be exposed to temperatures below –5 ° C or above +60 ° C*

- *Filling temperature of the fluid: the temperature of the product being filled must always be between +5 ° C and +60 ° C, it is possible to fill products over 60 ° C (and, in any case, within + 80 ° C) only for models expected*

1. Regarding to the manufacturing, assembly, storage and marketing phases of the object, we declare:
   - Implementing a company quality assurance and control system in compliance with Regulation (EC) No. 2023/2006;
   - Observe the provisions of the Art. 15, of the Regulation (EC) n ° 1935/2004 and s.m.i, on the subject of labeling;
   - Observe the provisions of the Art. 17, of the Regulation (EC) n ° 1935/2004 and s.m.i, in the matter of traceability.

2. Other specifications:
   It is specified that the company Tenco S.r.l. is not responsible for the work carried out on the object after leaving the factory or after issuing the test certificate in the case of installation and testing against Tenco S.r.l.
   It is also suggested to clean the object according to the "Installation, use and maintenance manual" after assembly and above all before contacting with foods.
3. This declaration is valid from the date below and will be replaced if substantial changes occur in the production of the object capable of changing certain essential requirements for compliance or when the legislative references cited in this declaration will be modified and updated in to request a new verification for compliance purposes.

4. The object is manufactured from various components, the following are the matrices of the components in contact with food:

A STAINLESS STEEL

Specific Requirements:

D. M. 21/03/1973 and subsequent updates and changes;

Stainless steel AISI 316 is included in Annex II section 6 of stainless steels which can be used in contact with foodstuffs according to the DM 21/03/1973 and s.m.i.

Conditions, indications and tolerances of use:

- Suitable for repeated use, short-term use, hot or at room temperature;
- Regarding to the machine, compliance with the Global Migration limits is stated (Test conditions: 100 ° C for 30 min considering the third attack).
- The Specific Migration of Chromium, Nickel, Manganese, respects the limit of 0.1 ppm for each metal (Test conditions: 100 ° C for 30 min considering the third attack).

B. PLASTIC (DIRECT CONTACT WITH FOOD)

Specific Requirements:

ARIANNA BIO:	*Special Bio-compound tube obtained from natural renewable sources, whose production allows a reduction of CO2 emissions in the atmosphere; high tenacity polyester yarn reinforcement.*
Regulation (EU) 10/2011 and subsequent amendments **Ministerial Decree of 03/23/1973 and subsequent amendments**	*The plastic used in the components was produced according to what is allowed by the Regulation (EU) n ° 10/2011.*
Types of food with which the article is intended to come into contact:	*Transport of food liquids, beverages, fruit juices, vinegar, wine and liqueurs with an alcohol concentration of up to 50%.*
Test conditions	
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*2÷0.5 cm2/cm3*
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE.	
Regarding to the item, compliance with the Global Migration limits is declared	
The article complies with the specific migration limits under the following conditions:	*Simulant B (3% acetic acid)* *Simulant C (ethanol 20% v / v)* *D1 simulant (ethanol 50% v / v)*
The analytical result obtained showed that the substances listed above comply with the	

Specific Migration Limit. *It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i ..*	
The raw material used for the wall does not contain, intentionally, one of the plasticizers that belong to the group of orthophthalates	
In the item, there are substances subject to restrictions by the current legislation.	○ *CAS 8013-07-8 Epoxidized Soya Bean Oil (ESBO)* ○ *CAS 6422-86-2 DOTP* ○ *CAS 68441-17-8 Oxidized polyethylene waxes* ○ *CAS // Zinc, salts* ○ *CAS // Calcium salts of fatty acid (DUAL USE art. 11 3a)*

EOLO PU FOOD	*Transparent tube with wall entirely in ether-based TPU, with reinforcing spiral in rigid shock-resistant ivory-colored PVC. Interior perfectly smooth.*
Regulation (EU) 10/2011 and subsequent amendments **Ministerial Decree of 03/23/1973 and subsequent amendments**	The plastic used in the components was produced according to what is allowed by the Regulation (EU) n ° 10/2011.
Types of food with which the article is intended to come into contact:	○ *A (aqueous food products with pH> 4.5 and aqueous containing up to 10% alcohol)* ○ *B (aqueous food products-acids pH <4.5)* ○ *C (aqueous food products-alcohol max 20%).* ○ *D2 (Food products based on fatty substances)*
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE.	
Regarding to the item, compliance with the Global Migration limits is declared	
The article complies with the specific migration limits under the following conditions:	*Simulant B (3% acetic acid)* *Simulant C (ethanol 20% v / v)*

	D2 simulant (olive oil)
Test conditions	
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*2÷0.5 cm2/cm3*
The analytical result obtained showed that the substances listed above comply with the Specific Migration Limit. *It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i ..*	
The raw material used for the wall does not contain, intentionally, one of the plasticizers that belong to the group of orthophthalates	

CRISTALLO EXTRA:	*Plasticized PVC pipe*
Regulation (EU) 10/2011 and subsequent amendments **Ministerial Decree of 03/23/1973 and subsequent amendments**	*The plastic used in the components was produced according to what is allowed by the Regulation (EU) n ° 10/2011.* *In particular:* *EU Regulation 10/2011* *Regulation 1935/2004 / EC* *Directive 2002/72 / EC, 2007/19 / EC and subsequent amendments* *Regulation EC 2023/2006 (GMP)* *Regulation 1895/2005 / EC* *And with the current Italian regulation, which:* *Ministerial Decree 174 of 24.09.2008 which replaces the Ministerial Decree 21/03/1973 and subsequent revisions and amendments*
Types of food with which the article is intended to come into contact:	*Transport of food liquids*
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE.	
Regarding to the item, compliance with the Global Migration limits is declared. **The article complies with the specific migration limits under the following conditions:**	

Test Conditions	
SIMULANT A:	*AQUEOUS 10% ETHANOL SOLUTION (for watery foods)*
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*The calculations consider that 1 kg of food that comes into contact with 6 dm2 of product.*
SIMULANT B:	*AQUEOUS SOLUTION OF ACETIC ACID at 3% (for acidic foods)*
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*The calculations consider that 1 kg of food that comes into contact with 6 dm2 of product.*
SIMULANT C:	*AQUEOUS SOLUTION OF 20% ETHANOL (for alcoholic foods)*
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*The calculations consider that 1 kg of food that comes into contact with 6 dm2 of product..*
SIMULANT D:	VEGETABLE OILS (for fatty foods)
Temperature and storage time in contact with the food product:	*2 hours at 40 °, repetitive use*
Ratio of contact surface to volume:	*The calculations consider that 1 kg of food that comes into contact with 6 dm2 of product..*

The article contains substances subject to restrictions under the current legislation:

SUBSTANCE	REF NO.	CAS. NO	SML (mg/Kg)	Restrictive group	Restrictions and specifications
Acid Tereftalatico, bis (2 ethiylhexyl)ester	92200	0006422-86-2	LMS = 60	32	-

			mg/Kg		
Soybean oil, epoxidized	88640	0008013-07-8	LMS = 60.0 mg/Kg	-	In the case of PVC gaskets used in the closure of glass jars containing formulas for children and follow on formulas, as defined by Directive 2006/141 / EC, foods based on cereals and baby foods for babies and children as defined in Directive 2006/125 / EC, the SML is lowered to 30 mg / kg. Oxiran <8%, iodine number <6.
Polyethylene w axes, oxidized	80070	0068441-17-8	LMS=60 mg/Kg	-	-
Calcium salts of fatty acid	-	-	-	-	no SMIL
DUAL USE (art 11 3a					
Zinc salts	-	-	LMS = 25 mg/Kg come Zinco	-	-
Ottadecile 3- (3,5 ditertbutil4idroxifenil propinato)	68320	002082-79-3	LMS = 6 mg/Kg	-	-
Vinilcloride	26050	0000075-01-4	Nd	-	1 mg / kg in the final product

The analytical result obtained showed that the substances listed above comply with the Specific Migration Limit.

It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i .

POLIETILENE HD-500:	*PE 500 FOOD GRADE NATURALE*
Regulation (EU) 10/2011 and subsequent amendments **Ministerial Decree of 03/23/1973 and**	○ The plastic used in the components was produced according to what is allowed by the Regulation (EU) n ° 10/2011.

subsequent amendments	○ Respects the requirements of Regulation (EC) n. 1935/2004, ○ Respect the relevant requirements of Regulation (EU) no. 10/2011, ○ They are manufactured according to Good Manufacturing Practice (GMP) as set forth in Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practices for materials and objects intended to come into contact with food products.
Types of food with which the article is intended to come into contact:	All types of food
Test conditions	
Temperature and storage time in contact with the food product:	2 h at 70°C
Ratio of contact surface to volume:	S/V = 5.7
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE.	
Regarding to the item, compliance with the Global Migration limits is declared.	Global migration test performed under standardized test conditions: OM3 in 10% ethanol (v / v), 3% acetic acid (weight / volume) e vegetable oil
Specific migration tests performed	3% acetic acid (2 h at 70 ° C) 10% ethanol (2 ha 70 ° C) Vegetable oil (2 h at 70 ° C)
In the article, there are substances subject to restrictions by the current legislation.	The following substances, subject to restrictions pursuant to Regulation (EU) 10/2011, are used in the products: Zinc stearate = Group SML 25 mg / kg (expressed as zinc) The following substances, identified as dual-use additives pursuant to Regulation (EU) 10/2011, are

	used in the products: Calcium stearate (CAS No. 001592-23-0)
The analytical result obtained showed that the substances listed above comply with the Specific Migration Limit. *It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i .*	

RECOVERY VESSEL MOULDED WITH POLYMER:	*MAKROLON 2856*
Regulation (EC) 1935/2004 **Commission Regulation (EU) 10/2011**	Makrolon® 2856 550115 is manufactured by applying the rules on good manufacturing practice (GMP) which are considered appropriate for plastic raw materials as required by Regulation (EC) 1935/2004 and (CE) 2023/2006. This includes the use of procedures to cover traceability from the arrival of starting materials to the outgoing food contact material. Makrolon® 2856 550115 is manufactured only with monomers and additives authorized pursuant to regulation (EU) no. 10/2011 of the Commission, dated January 14, 2011, concerning "plastic materials and articles intended to come into contact with food". All the monomers and additives used for the manufacture of Makrolon® 2856 550115 are listed in Annex I of the Commission Regulation (EU) 10/201

Specific limits
The following table provides information on specific restrictions that must be observed based on
Regulation (EU) n. 10/2011 of the Commission

CAS NUMBER	NAME	RESTRICTIONS QM = maximum permitted quantity of plastic residue; SML = specific migration limit in food or simulant)
000080-05-7	2,2-Bis (4-hydroxyphenyl) propane	SML = 0.6 mg / kg, not to be used for the manufacture of infant feeding in polycarbonate bottles
000102-09-0	Diphenyl carbonate	SML = 0.05 mg/kg
085116-93-4	Acids, fats (C8-C22), esters with pentaerythritol	No restrictions

Rating:
The limits mentioned above were met in exemplary surveys on virgin material

representative of the composition of Makrolon® 2856 550115. The material has been tested with food simulant for 2 hours at 100 ° C (or boiling point) for 10 days at 40 ° C and assessed for a surface / volume ratio of 6: 1.

END ADJUSTER, RIGID CONNECTION AND ELBOW BEND MOULDED WITH POLYMER	*HE125MO* *polypropylene homopolymer*
DECLARATION OF CONFORMITY TO FOOD CONTACT RULES This product meets the applicable requirements on substances used in the manufacture of materials and articles or components of articles intended to come into contact with food as described in the legislation and standards mentioned below. European Union The regulations listed below are harmonized European legislation and are directly applicable in all EU Member States. Therefore, the national legislation implementing these regulations is not mentioned separately	
Regulation (EU) n. 10/2011 and subsequent amendments	All the monomers and additives used are listed in Annex I of this Regulation. For any applicable restrictions, see the chapter "Migration test".
Regulation (EC) n. 2023/2006	This material was manufactured in compliance with the relevant requirements of good manufacturing practices for articles intended to come into contact with food
Regulation (EC) n. 1895/2005	BADGE, NOGE and BFDGE are not used for the production of this polymer
Commission regulation (EC) n. 450/2009 on active and intelligent materials and articles	It is not applicable to the above polymer resin.
Additional national legislation in EU Member States (as amended to date) Aid for polymerization production, aid to polymerization, dyes and solvents, if not already listed in Annex I of Regulation (EU) n. 10/2011 can be used based on national and subject approval to mutual recognition.	Process chemicals used for the production of this grade are permitted by PH 13.06.2018 Ed. 36 polypropylene HE125MO
LIMITS AND MIGRATION TEST	The product contains traces of aluminum, which is regulated by a specific one EU migration limit (Commission Regulation 10/2011, Article 6.3.a and Annex II)

	and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg / kg expressed as Al). Representative tests of the worst case (3% acetic acid; 4h / 100 ° C; S / V Ratio 6) did not show any migration greater than 0.04 mg / kg. The product may contain a residual component from the catalyst system it is regulated with a specific migration limit in the EU. 95% ethanol migration test for 10 days at 60 ° C showed a significantly lower level of migration than SML, then applying a standard surface volume ratio of 6, this SML cannot be exceeded based on any foreseeable conditions of use. Other monomers and additives used are not regulated with specific migration limits The substances also authorized as direct food additives ("dual-use additives") are or not used for the manufacture of this product, type of non-migration or alone present in quantities that do not allow a relevant contribution in the event of migration to exceed the limits set in the applicable food regulations.
MIGRATION TEST	Under Article 12 of Commission Regulation (EU) 10/2011, Article 12 of Swiss Ordinance 817.023.21 and article 2.12 of the Chinese standard GB4806.1 the overall migration should not exceed 10 mg / dm² from plastic materials and objects, with the exception of plastic materials and articles intended to contact children or babies baby food (60 mg / kg) A representative sample of this or a similar material, tested for 2 days at 20 ° C in isooctane (1 mm plate / total immersion) it did not exceed the limit of 10 mg / dm² for overall migration.
NON-INTENTIONALLY ADDED SUBSTANCES	Commission Regulation (EU) 10/2011 notes that not all contaminants and reaction products of authorized substances monomers and additives may be listed in its Annex I. The identification of unlisted migrants may therefore not be an exclusion criterion in itself. However, it is

	necessary to perform a toxicological evaluation of these migrants. The main fractions of NIAS in polyolefins are oligomers, which are inevitably formed during polymerization and cannot be removed. A recent joint study on polyolefin producers has shown that oligomers migrate from everyone the types of polyolefins consist only of linear and branched alkanes (POSH) and alkenes (POMH), non-cyclic or aromatic compounds were found The toxicological evaluation of these migrants concluded that they are sufficient characterized by the existing global migration limit. Furthermore, a variety of representative Borealis products were evaluated, covering the entire range of Borealis products in relation to the migration of NIAS by renowned test institutes. In addition to oligomers, the typical NIAS are the reaction and antioxidant decomposition products, many of which are known as "Arvin substances". Another joint sector study confirmed that none of these substances Arvin is genotoxic and therefore can be classified at least as "Cramer-class" III ", which allows a daily consumption of 90 μg / person / day.

COVER VESSEL AND FLOAT MOULDED WITH POLYMER	*Polipropilene Eltex P HCW280*
EU FOOD CONTACT: DECLARATION OF CONFORMITY (DOC)	
THIS POLYMER IS IN ACCORDANCE WITH THE RELEVANT REQUIREMENTS OF:	Regulation (EC) n. 1935/2004 of the European Parliament and of the Council, of 27 October 2004 on materials and objects intended to come into contact with food Regulation (EU) n. 10/2011 of January 14, 2011, relating to plastic materials and objects intended to come into contact with food, 321/2011 (1/4/2011), 1282/2011 (11/28/2011), 1183/2012 (11/30/2012), 202/2014 (3/3/2014), 2015/174 (5/2/2015), 2016/1416 (8/28/2016), 2017/752 (4/28/2017) Regulation (EC) n. 2023/2006 of 22 December 2006, relating to good manufacturing practices for materials and objects intended to come into contact with food (GMP) and subsequent amendments. NIAS (Unintentionally Added Substances) and

	Identified IAS (Intentionally Added Substances) present in this grade were assessed at risk in accordance with Article 19 of the Plastics Regulation (10/2011) and comply with the relevant requirements of the framework regulation (1935/2004).
INFORMATION ADAPTED ON THE SUBSTANCES USED FOR WHICH RESTRICTIONS ARE INTENDED	Monomers subject to specific migration limit (SML) are not used.
Indicative modeling results in the new, more severe test conditions 10 days / 60 ° C, in food simulants A, B, C, D1 and D2 and at a surface volume ratio of 6 dm-1 ("EU cube") indicate that the SMLs listed above can be overcome with food simulants D1 and D2. Indicative global migration tests carried out on this type of polymer on film or thin plate, under conditions 10 days / 40 ° C, in food simulants A, B and D2 show that the overall migration limit of 10 mg / dm² is not exceeded.	
ADEQUATE INFORMATION RELATING TO SUBSTANCES WHICH ARE SUBJECT TO RESTRICTION ON FOOD.	Glycerol Monostearate (E471) (CAS nb 31566-31-1) and sodium benzoate (E211) (CAS nb 532-32-1) are approved as food additives (dual-use additives). They are present, as an additive, in the aforementioned degree.
This polymer contains two additives subject to specific migration limits (sml) of 5 mg / kg and 0.6 mg / kg.	
Phthalates are not used as additives or raw materials in the production of the degree indicated above.	
OTHER ADDITIVES:	Bovine spongiform encephalopathy (BSE) Transmissible spongiform encephalopathy (TSE) This grade contains stearate (s) as an additive (s). We have received the following guarantees from our suppliers: 1. The raw materials used in the production of animal derived additives are classified in cat 3 according to regulation (CE) n. 1069/2009, which repeals regulation (EC) no. 1774/2002 and its implementation Regulation 142/2011, or come from countries considered BSE exempt.2. The sites of production of these additives of animal origin are approved as oleochemical plants cat 3 by local authorities and have obtained the relative certification with a registration number. Beef tallow processing includes high temperatures (under pressure or not) for a defined duration, as prescribed by

	Regulation 142/2011, in order to eliminate the risk of BSE contamination. 3. It is also claimed that BSE has never been found in beef and in the World Health Organization (CHI) said that tallow does not represent a risk to human and animal health (WHO / CDS / VPH / 95,145). Furthermore, during pelletization and conversion, polyolefinic plastics are exposed to shear stresses and temperatures ranging from 160 ° C to 300 ° C for 20 seconds to a few minutes. These next steps to help ensure the complete protection of people's health in relation to TSE for the plastic materials used food applications or the like.
GENETICALLY MODIFIED ORGANISMS (GMOs)	Among the great variety of polymeric additives and starting substances used, only some of them can be emitted of genetically modified organisms. We would like to comment on the relevance of the gene modification techniques to plastic materials. The most significant fact is that the starting substances or additives (in the sense of Regulation 10/2011) deriving from raw materials issued by genetically modified organisms produced through a multi-step conversion and / or purification process, which involves aggressive conditions such as high temperature and pressure, as well as the action of chemically reactive substances. The final plastic the materials themselves are produced under high temperature conditions and are further presented during conversion processes (extrusion, molding) at high temperature for a significant period of time. Based on current scientific knowledge, it can be stated that no DNA is no protein from a given the organism (genetically modified or not) can resist and go through such a series of treatments. Therefore, their presence in our polymers and in the plastic articles produced by them is highly unexpected. In conclusion, we confirm that the above polymer is safe to be produced, processed and used, even if it is manufactured from starting substances or containing additives which may be from genetically modified organisms source.

GASKET WITH ECOPUR LIPS	*U-500 H-PU*
Regulation (EU) 10/2011 and subsequent amendments Ministerial Decree of 03/23/1973 and subsequent amendments	*The plastic used in the components was produced according to what is allowed by the Regulation (EU) n ° 10/2011.* *• Regulation (EC) n. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and objects intended to come into contact with food and repealing Directives 80/590 / EEC and 89/109 / EEC (Official Journal L 338)* *• Regulation (EC) n. 2023/2006 of the Commission, dated December 22nd 2006, concerning practical manufacturing production (GMP) for materials and articles intended to come into contact with food (Official Rivista L 384)* *• Commission Directive 2002/72 / EC of 6 August 2002 on plastic materials and objects intended to come into contact with food products (Official Journal L 220)* *• Regulation (EU) n. 10/2011 of the Commission, dated 14 January 2011, relating to plastic materials and articles intended to come into contact with food* *• Regulation (EU) n. 1282/2011 of the Commission, of November 28, 2011, which amends and amends Regulation (EU) n. 10/2011 of the Commission (Official Journal L 328)* *• In line with Article 17 of Regulation (EC) No. 1935/2004, the traceability of all materials and articles put into circulation are ensured by an appropriate system.* *• The compound meets the specifications of the positive list at 21 CFR 177.2680 "Polyurethane resins" of the Food and Drug Administration (FDA), USA.*
Types of food with which the article is intended to come into contact:	*Generic food products*
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE	
Regarding to the article in question, compliance with the Global Migration limits is declared	
Specific migration tests performed	

<table>
<tr><th colspan="2">Test conditions</th></tr>
<tr><td></td><td>Acetic acid with 3% acetic acid solution
Test lasting 10 days at 40 °
Overall migration <1
Acceptable volume / surface ratio
[ML / dm²] <17

Aliphatic isooctane
Test lasting 2 days at 20 °
Overall migration 4
Acceptable volume / surface ratio
[Ml / dm²] 7

Aliphatic ethanol
Test lasting 2 hours at 60 °
Overall migration 18.5
Acceptable volume / surface ratio
[Ml / dm²] 308</td></tr>
<tr><td colspan="2">Residual content of isocyanate according to DIN EN 13130-8
The maximum residual isocyanate content (calculated as NCO) relative to (EU) 10/2011 may not exceed 1 mg / kg of material

The determined quantity is below the detection limit (<0.2 mg / kg)
Specification of primary aromatic amines according to EU no. 10/2011 ANNEX II

The specific migration limit of primary aromatic amines is 0.01 mg / kg of food product.
The determined quantity is below the detection limit (<0.01 mg / kg)</td></tr>
<tr><td>In this item, there are substances subject to restrictions by the current legislation.</td><td>The gaskets usually have a small contact area and also a short exposure time (<1 hour) with food products.

Therefore, the general migration tests were performed in a manner adequate to the standardized OM3 test conditions (EU 10/2011, Annex V, table 3).

That corresponds to all the contact conditions that include heating at 70 ° C for a maximum of 2 hours, or up to 100 ° C for a maximum of 15 minutes, which are not followed by a long-term room or temperature storage chilled.

The calculation of the acceptable ratio of volumetric food products per sealing surface is based on the verification of compliance by residual content per contact surface with food as indicated in EU 10/2011 Annex I and Annex V 2.1.8.

Migration tests according to ON EN 1186-3 and -14 respectively EU 10/2011 with the simulant described above cover the food groups indicated in table 2 of the EU Annex 11/2011.</td></tr>
<tr><td colspan="2">The analytical result obtained showed that the substances listed above comply with the Specific Migration Limit.</td></tr>
</table>

It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i .

C. RUBBER (DIRECT CONTACT WITH FOOD)

PHARMAPRESS:	*Transparent tube in hygienic TPE-S rubber, with high tenacity polyester textile reinforcement. Highly neutral to odors and flavors, it preserves the organoleptic properties of the substances transported. Resistant to hydrolysis and microbial attacks. Curing free material.*
Regulation (EU) 10/2011 and subsequent amendments **Ministerial Decree of 03/23/1973 and subsequent amendments**	*The rubber used in the components was produced according to what is permitted by the Regulation (EU) n ° 10/2011*
Types of food with which the article is intended to come into contact:	*Generic food products*
THE ARTICLE HAS BEEN TESTED FOR GLOBAL MIGRATIONS AND FOR SPECIFIC MIGRATIONS, SIMULATING THE CONDITIONS OF CONTACT IN THE PREVIOUSLY WORST USE.	
Compliance with the Global Migration limits is declared	
Specific migration tests performed	*A (aqueous pH> 4.5 and aqueous containing up to 10% alcohol)* *B (aqueous-acids pH <4.5)* *C (water-alcohol max 20%)* *D1 (aqueous-alcoholic beverages max 50%)* *D2 (Food products based on fatty substances)* *96% Ethanol*
Tests conditions	
Temperature and storage time in contact with the food product:	*10 days at 40°C*
Ratio of contact surface to volume:	*2÷0.5 cm2/cm3*
	Simulant B (3% acetic acid), *Simulant C (ethanol 20% v / v)* *D1 simulant (ethanol 50% v / v)* *D2 olive oil simulant* *EtOH simulant (96% v / v)*

TENCO S.R.L. unipersonale
Via Arbora 1
16030 AVEGNO (GE) Italy
P.IVA / VAT 03111170100

tecnica e tecnologia del confezionamento

tel +39-0185-79.556 r.a.
fax +39-0185-79.412
info@tenco.it
www.tenco.it

The raw material used for the wall does not contain, intentionally, one of the plasticizers that belong to the group of orthophthalates
The tube complies with the requirements of the USP class VI.
the analytical result obtained showed that the substances listed above comply with the Specific Migration Limit. *It also declares compliance with the Specific Migrations in a simulant worst case of the substances present in Annex II of Regulation (EU) n ° 10/2011 and s.m.i ..*

Date: 13.04.2019

TENCO S.R.L.
Giuseppe Tenco