



Polykeg S.r.l.  
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*Declaration of conformity N° 4 - Rev.04*

**DECLARATION OF CONFORMITY OF MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH  
FOOD PRODUCTS**

1. This declaration applies to the following products:

**Single-use plastic kegs with bag with a capacity of up to 30 litres, belonging to the models  
PREMIUM, SMART, BASIC, PRO with A, S, D, G, M and K valves**

**EUROPEAN UNION**

2. With this document we declare that the products supplied for prolonged contact, up to room temperature, for the following drinks:

01.01 Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:

- A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract
- B. Cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate

01.02 - Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.

01.03 - Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors

**are compliant**

with the following European Community legislation:

- Regulation (EC) No. 1935/04 and subsequent updates, in particular article 3, article 11, paragraph 5, article 15 and article 17
- Regulation (EC) No. 1895/05 on epoxy derivatives and subsequent updates
- Regulation (EU) No. 10/2011 and subsequent updates
- EN 602 standard concerning the chemical composition of aluminium and aluminium foils for use in articles intended for contact with food



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and with the following Italian legislation:

- Ministerial Decree 21/03/73 and subsequent updates and amendments
- Presidential Decree 777/82 and subsequent updates and amendments

3. The products intended for direct and indirect contact with the foods mentioned in point 1 are manufactured with different components, consisting of the raw materials shown in the following table:

Component	Raw material
Bag	OPA + adhesive + ALU + adhesive + OPA + PE (side in contact with food)
Valve	Polyoxymethylene copolymer (POM), Polypropylene (PP), Styrene-ethylene-butylene copolymer (SEBS / TPE) and Polifenilsulfone (PPSU)
	Rubber
Pouring tube kit with adapter and stopper for bag	Low density polyethylene (PE), Polypropylene (PP)

4. The raw materials of the various components contain substances subject to restrictions in the above legislation.

The substances subject to specific restrictions are listed in *Annex 1*, which is available on specific request, upon signing the confidentiality agreement.

5. The global migration limit, together with the specific restrictions of the substances listed in *Annex 1*, the primary aromatic amines, metals and colourings are respected under the conditions of use mentioned in point 2 of the declaration.

**Test conditions:**

Simulant	Time and temperature
B: Acetic acid 3% v/v	10 days at 60°C
D1: Ethanol at 50% v/v	10 days at 60°C

The ratio between the contact surface for the food product and the volume used to determine the product conformity ranges from 1 to 2 cm<sup>2</sup>/cm<sup>3</sup>.



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6. There is no Bisphenol A in the product and there are no plans to add this substance in the production process. This statement is supported by analytical tests conducted following the entry into force of Regulation (EU) No. 2018/213.
7. In the materials of the various components there are substances regulated by Regulation (EC) No. 1333/2008 and by Regulation (EC) No. 1334/2008 (substances also called "dual use" additives). According to experimental data and/or theoretical calculations, these substances comply with the provisions of Article 11, paragraph 3, letters a and b, of Regulation (EU) No. 10/2011 and subsequent amendments, and the Ministerial Decree of 21 March 1973.  
These "dual use" substances are listed in *Annex 1*.
8. In support of the above, the company declares to have at the disposal of the competent Authority:
  - test reports on the finished product and
  - other supporting documentation required pursuant to Regulation (EC) No. 1935/2004, art. 16, paragraph 1.
9. PolyKeg S.r.l. applies the Good Manufacturing Practices and a Quality Assurance System as required by Regulation (EC) No. 2023/2006 "Good manufacturing practice for materials and articles which are intended to come into contact with food".

#### USA

10. We hereby declare that the product listed in paragraph 1 of this declaration provided by PolyKeg S.r.l. is suitable for contact with food conforms to the American legislation - Food and Drug Administration (FDA). The products can be used safely during the processing, handling and packaging of foods in compliance with the above regulation.
11. Based on the statements made by suppliers of the raw materials, the product complies with the standards listed below (Food and Drug Administration (FDA), Title 21 of the Code of Federal Regulations):  
For the bag:
  - FDA 21CFR 177.1520 (olefin polymers – PP and PE)
  - FDA 21CFR 177.1630 (polyethylene phthalate polymers – PET)
  - FDA 21CFR 177.1500 (polyamide resins)
  - FDA 21CFR 177.2470 (polyoxymethylene copolymer)
  - FDA 21CFR 177.1655 (polysulfone resins)
  - FDA 21CFR 178.3297 (colourings for polymers)
  - FDA 21CFR 177.2600 (butyl rubber)

Layer	Standard
PE film (side in contact with food)	FDA 21CFR § 177.1520(b), (c)2.1, (c)3.1a – Olefin polymers FDA 21CFR § 178.2010 – Antioxidants/stabilisers for polymers FDA 21CFR § 170.189 – Food additives



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Adhesive	FDA 21CFR § 175.105 – Adhesives – compliant composition
OPA film	FDA 21CFR § 177.1500 – Nylon resins
Adhesive	FDA 21CFR § 175.105 – Adhesives – compliant composition
ALU film	although not listed in any specific monograph, aluminium foil is generally recognised as safe (GRAS), and the oils used in its production processes comply with § 178.3910
Adhesive	FDA 21CFR § 175.105 – Adhesives – compliant composition
OPA film (external side)	FDA 21CFR §§177.1500 – Nylon resins

- The product is also manufactured in accordance with Good Manufacturing Practices (GMP) under FDA Title 21, CFR 174.5.
- This declaration cannot be extended to cases in which the product was used for purposes other than those for which it was requested and/or declared suitable by PolyKeg S.r.l. in this declaration, as well as for methods of use other than those listed on the Product Sheet and in the Instruction Manual. In this case PolyKeg S.r.l. is relieved of any responsibility and it is up to the end user to check the suitability of the material for the new conditions of use.
- This declaration is valid from the date shown below and will be replaced if there are substantial changes to the production of the material which may alter certain essential requirements for conformity, or when the legislative references above are modified and updated and therefore require new verification for conformity purposes.

Grumello del Monte (BG), Italy, on 14/12/2021

**First and last name:** Sergio Sonzogni

**Role:** Managing Director

**Signature/ (company stamp):** .....

**POLYKEG S.R.L.**  
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