



Polykeg S.r.I. Via P.Nenni, 51 24050 Calcinate (BG) - Italy Ph. +39 035 4522245 - Fax +39 035 4522914 www.polykeg.it - info@polykeg.it

Declaration of conformity No 1A - 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 in GREEN, AMBER, BLACK, SILVER, belonging to the PREMIUM, SMART, BASIC, PRO models with a capacity of up to 30 litres 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 %.

and for SILVER-coloured kegs only:

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





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- Regulation (EU) No. 10/2011 and subsequent updates

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
Keg	PET + Nylon + Masterbatch colouring
Valve	Polyoxymethylene copolymer (POM), Polypropylene (PP), Styrene-ethylene-butylene copolymer (SEBS / TPE) and Polifenilsulfone (PPSU)
	Rubber
Pouring tube	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
C: Ethanol at 20% v/v	10 days at 60°C

Test conditions (for silver bottle):

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





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For the global migration of the green and black bottle, and for the specific migration of some restricted substances for the silver bottle the following test conditions were used:

Simulant	Time and temperature
B: Acetic acid 3% v/v	10 days at 40°C
C: Ethanol at 20% v/v	10 days at 40°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 cm²/cm³.

- 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 foods and 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. The products comply with the standards listed below, for repeated contact with the drinks listed in point VI (A, B, C), according to the conditions of use from D to F of Tables 1 and 2 of Title 21, CFR 176.170 (c) of the FDA.





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The product is approved for contact with all types of foods except those with an alcohol content over 15%.

12. 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 Code of Federal Regulations:

- 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)

Therefore, we declare that all our packaging and packaging components that are normally used for products intended for contact with food comply with the requirements of the above legislation.

- 13. The product is also manufactured in accordance with Good Manufacturing Practices (GMP) under FDA Title 21, CFR 174.5.
- 14. 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.
- 15. 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.

Calcinate (BG), Italy, on 15/06/2020

First and last name: Sergio Sonzogni

Role: Managing Director

POLYKEG S.r.l. Via Pietro Nenni, 51 24050 CALCINATE (BG) - Italia P.J.C.F. 03766000164

Signature /(company stamp):