



Declaration of Conformity for materials and items used for food-contact

Hereby declare

M41221
IMBUTO CM.21 BIANCO

COMPLY

with the following UE regulations:

- **Regulation (EC) 178/2002 and subsequent updates**
concerning the general requirements of food law
- **Regulation (CE) Nr.1935/2004 dated 24 October 2004 and subsequent updates**
concerning items and materials used for food-contact
- **Regulation (UE) Nr. 10/2011 dated 14 January 2011 and subsequent updates**
concerning plastic items and materials used for food-contact
- **Regulation (CE) Nr. 2023/2006 dated 22 December 2006 and subsequent updates**
concerning the best production practices applied to items and materials used for food-contact (GMP)

IS ACCORDING TO

and with the following Italian Decrees:

- **Ministerial Decree dated 21 March 1973 and subsequent updates and modifications**
Hygienic discipline regarding packages, containers, tools, that come into contact with food-related substances or personal use substances.
- **Presidential Decree 777/1982 and subsequent updates**
concerning materials and objects intended to come into contact with food
- **D. Lgs nr. 29 dated 10 February 2017**
Discipline of sanctions in case of violation of the dispositions according to the regulations (CE) nr. 1935/2004, nr. 1895/2005, nr. 2023/2006, nr. 282/2008, nr. 450/2009 and nr. 10/2011, regarding materials and objects intended for food products.
The product in question is manufactured with the following materials, all of which are food-compliant

HDPE CAS 9002-88-4

BIANCO

which do not contain substances subject to restrictions and respect the global migration limits in the following test conditions
(Tests were run assuming that 1 Kg of nourishment came into contact with 6 dm² of product):

Simulant	time	Temperature
A for prolonged contact	10 days	40°C ° (OM2)
B for prolonged contact	10 days	40°C ° (OM2)
D1 for prolonged contact	10 days	40°C ° (OM2)
D2 (isooctane) for prolonged contact	2 days	20°C ° (conversion table D.M. 21/03/73) (OM2)

The global migration limit of the master-batch, where present, is respected in the above-mentioned conditions.

This statement is supported by analytical proofs or according to calculations on the substance's migration tested according to the UE Directive 82/711 and 85/572 and subsequent updates and to Decree nr. 338 dated 22/07/1998.

In the product there are no substances regulated by Regulation (EC) 1333/2008 and by Regulation (EC) 1334/2008 (substances also called "dual use additives"). According to experimental data and / or theoretical calculations, these substances comply with the provisions of art. 11 paragraph 3, letter a, b of Regulation (EU) 10/2011 and the Ministerial Decree of 21/03/1973.

The toxicological risk assessment in simulant Acetic Acid 3% w / v of Metals, Lanthanides, Aromatic Amines and Bisphenol A was found to be negative pursuant to Reg. (EU) 2020/1245.

The absence of BPA in the sample is declared in accordance with COMMISSION REGULATION (EU) 2024/3190 of December 19, 2024 and the requirements of Articles 3, 15 and 17 of Regulation (EC) No. 1935/2004.

The Company declares that in the production process no substances capable of causing allergies are intentionally added (Ref. EU Reg. 1169/2011)

Sample according to the parameters checked is suitable for food-contact

The applied contact-conditions make the product suitable in the following conditions:

under any room temperature or below temperature prolonged exposition, including heating up to 70°C for 2 hours or heating up to 100° for 15 minutes (OM2). To support what previously mentioned, this firm declares to have at disposition of the client and of the competent Authority the following documents: tests reports made on the finished packaging, other documentation in support requested according to the EU Reg. 10/2011 and subsequent updates.

This declaration validity starts from the date below and will necessary be reviewed in case of any substantial change in the material production that would mutate some essential requirements regarding conformity or if the legislative references cited are modified and updated which would require a new verification for compliance purposes.

The declaration is drawn up in accordance with current legislation and is intended for: ETRA OY

Copiano, 06/03/2025

Stefano Grecchi

Consigliere d'Amministrazione

