

**DECLARATION OF COMPLIANCE TO REGULATIONS ON  
MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD  
as per article 16 of REGULATION (EC) No 1935/2004**

I, the undersigned, Mr G rald SOULAGNET

Company: **TRELLEBORG CLERMONT-FERRAND SAS**

Address: ZI La Combaude - Rue de Chantemerle CS 10725- 63050 Clermont-Ferrand Cedex 2

Acting in the capacity of: R&D Material Manager

Hereby declare that the article referenced as follows: **ALCODIAL**, is composed of layers of plastic and rubber strongly bound.

The material intended to come into contact with food entering into the composition of this product belongs to the Plastics category.

I declare that our product complies with the requirements of:

- Regulation EC N  1935/2004 of 27th October 2004 modified;
- Regulation EC N  2023/2006 of 22nd December 2006 modified;
- Regulation EC N  10/2011 of 14th January 2011 modified;
- Regulation (EC) No 2024/3190 of 19th December 2024.

Compliance is declared:

- subject to respect of the storage, handling and utilisation conditions specified by Trelleborg , subject to the use of original spare parts, and taking into account the specific characteristics of our product.
- with the following restrictions, where applicable:
  - In the case of modification of the physicochemical properties of the food in contact with the material, modification of the said food, modification of the contact conditions (temperature, length of time, etc.) and in the case of modification of the process or cleaning and disinfection conditions as defined by Trelleborg, the recipient of this declaration must check the continuing fitness for use of the material or article referred to herein.
  - Any changes in the material or article or its use must be submitted for reassessment of compliance.

This declaration of compliance is based on the following:

- Declaration(s) of the suppliers of materials
- Overall migration analysis Simulants list

The tests were realized in these simulants according Regulation EC N  10/2011 of 14th January 2011.

- A : Ethanol 10%
- B : Acetic acid 3%
- C : Ethanol 20%
- D1 : Ethanol 50%
- D2 : Vegetal oils

The tests were realized according conditions MG3 (2h at 70 C) for simulants A, B and C.

The tests were realized according conditions 30 mn at 40 C for simulant D2.

IANESCO test report N RE-16/10184 dated 20/06/2016 (Institut Fran ais de Potiers)

The tests were realized according conditions 24 hours at 40°C with ethanol 95% according to IANESCO report N°E18-01436 of 16 February 2018.

This declaration is valid on the date of delivery of the material or equipment. It will be renewed in all cases where compliance with the above is no longer assured (change of material, change in regulations before delivery of the delivery of the material or equipment).

The declarant shall make available to the competent authorities appropriate documentation to demonstrate this compliance.

We also confirm that our product complies with requirements of these countries:

Unites States of America:

- FDA requirements: FDA CFR 21 § 177.1520
- Pharmacopeia requirement: USP class VI

We also confirm that this hose complies with REACH regulations without restriction, and does not contain

- no phthalates
- no bisphenol A
- no MOAH or MOSH
- no ingredients of animal origin

Clermont-Ferrand, 01/02/2025  
R&D Material Manager  
Gérald SOULAGNET

