

**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 Gérald SOULAGNET

Company: TRELLEBORG INDUSTRIE 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 materials intended to come into contact with food entering into the composition of the article referenced by the client as follows: **BIOVAST**, belong to the category of materials RUBBER (as per Annex I of regulation EC 1935/2004).

I declare that our product complies with the requirements of:

- Regulation (EC) No 1935/2004 of 27<sup>th</sup> October 2004 modified;
- Regulation (EC) No 2023/2006 of 22<sup>nd</sup> December 2006 modified;
- French Regulation dated 1994/11/09 on rubber materials: IANESCO Tests reports IANESCO N°E17-15890-1 & N°E17-15890-2 dated 28 July 2017.

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 according to French Regulation dated 1994/11/09 on rubber materials, category D.

Stimulants list

- B : Acetic acid à 3%
  - Ethanol 70%(covering simulants A, C & D1)
  - Isooctane - Ethanol 95% (as a substitute of the D2 simulant as stipulated in directive 97/48.
- Analysis of substances subject to limitation (including specific migration) according to French Regulation dated 1994/11/09 on rubber materials, category D.

For reasons of confidentiality, we do not specify substances and associated LMS.

This declaration is valid on the date of delivery of the material or article. It must be renewed whenever compliance to above is no longer ensured (change of material or change in regulations before delivery of the material or article).

We keep all appropriate documentation in support of the said compliance at the disposal of the relevant authorities.

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

**Germany**

- complies with Category 2 Recommendation XXI; Commodities based on natural and synthetic rubber; Migration - Test BfR N° H-223290-12-Bg dated 14/11/2012.

**United States**

- complies with FDA CFR 21 § 177.2600 (e), Rubber articles intended for repeated use -

For information, we confirm furthermore that this hose, as all our hoses rubber intended for the food contact, contains no phthalate and no bisphenol A.

Clermont-Ferrand, 19/09/2017

R&D Material Manager  
Gérald SOULAGNET



**Trelleborg Industrie SAS**  
au capital de 10 527 685 €  
ZI La Combaude  
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F - 63050 Clermont-Ferrand Cedex 2  
RCS Clermont-Ferrand B 391 933 397