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, Gérald SOULAGNET

Company: TRELLEBORG CLERMONT-FERRAND SAS
Address: ZI La Combaude - Rue de Chantemerle CS 1 0725- 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 and entering into the composition of the article referenced as **LACTADIAL**, belong to the category of materials RUBBER.

I declare that our product complies with the requirements of:

- Regulation (EC) No 1935/2004 of 27th October 2004 modified;
- Regulation (EC) No 2023/2006 of 22nd December 2006 modified;
- Regulation (EC) No 2024/3190 of 19th December 2024;
- French Regulation dated 2020/08/05 on rubber materials

Compliance is declared:

- Subject to compliance with storage, handling and usage 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 2020/08/05 on rubber materials, category D, 3x2h at 40°C

Simulants list:

- B: Acetic acid 3%
- D1 Ethanol 50% (covering for simulant A and C)

- Analysis of substances subject to limitation (including specific migration) according to French Regulation dated 2020/08/05 on rubber materials, category D, 3x2h at 40°C.

Simulants list:

- B: Acetic acid 3%

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

BU Fluid Handling Solutions
Trelleborg Clermont-Ferrand SAS - ZI La Combaude - Rue de Chantemerle CS 10725
63050 Clermont-Ferrand Cedex 2 - France
Tel. +33 (0)473 25 8938 - Fax +33 (0)473 25 8222 - gerald.soulagnet@trelleborg.com - www.trelleborg.com

SAS au capital de 10 527 685 € - RCS Clermont-Ferrand B 391 933 397 - SIRET 391 933 397 00013 - APE 2219Z - TVA FR 56 391 933 397

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

- BfR Category 2 Recommendation XXI; Commodities based on natural and synthetic rubber.

United States

- FDA CFR 21 § 177.2600 (e), Rubber articles intended for repeated use.
- FDA CFR 21 § 177.121 0, Closures with sealing gaskets for food containers. Determination of extractable substances in 8% ethanol.

China

- GB4806-1.2016 and more specifically to GB4806.11-2016, national food safety standard for rubber material and product intended for food contact.
  - Global migration test conditions: 2h at +70°C — material for repeated contact
  - Simulants: 4% acetic acid and 50% ethanol.

Brazil

- Anvisa legislation. Resolution 123/2001, “Approving Technical Regulations on Packaging and Elastomeric Equipment in Contact with Food” including

-Part III of RDC No. 326/2019 - Positive list of additives for the preparation of polymers in contact with food.
-RDC 51/201 0 being the reference for total migration
-RDC 52/201 0 - Use of dyes and pigments for pigmented elastomers (note: item not relevant to our equipment, as our hoses do not use pigments or dyes on the face in contact with food).

Furthermore, I confirm that this hose complies, without restriction, to the latest REACH regulation and contains

- no phthalate no bisphenol A
- no MOAH or MOSH
- no animal derived ingredients,
- no ethyl alcohol or intoxicant and ethyl alcohol has not been used in the manufacturing process, and it is not manufactured on equipment used for manufacturing of products containing ingredients of animal origin and is not stored together with products containing ingredients of animal origin.

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

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afaq ISO 9001 Qualité AFNOR CERTIFICATION

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