



DECLARATION OF COMPLIANCE

Statement of compliance with European Union regulation
(EC) no 1935/2004 on materials and articles intended to come into contact with food
Requirement per Article 16 of EC 1935/2004



Graco Inc. declares that the equipment listed below contains materials that have been demonstrated to meet the requirements of Regulations: **EC 1935/2004** of 27 October 2004 and **EC 2023/2006** of 22 December 2006

Model Saniforce 515 Sanitary Diaphragm Pumps

Part No FD5111, FD5611, FD6111, FD5113, FD6113, FD5613, FW5111, FW5611.

Materials used in this equipment that are intended to contact food belong to the groups of materials listed in Annex 1 (EC) 1935/2004 (List of groups of materials and articles which may be covered by specific measures)

- | | |
|---|--|
| <input type="checkbox"/> Adhesives (2) | <input checked="" type="checkbox"/> Plastics (10) |
| <input type="checkbox"/> Ceramics (3) | <input type="checkbox"/> Printing Inks (11) |
| <input checked="" type="checkbox"/> Rubbers (5) | <input type="checkbox"/> Silicones (13) |
| <input checked="" type="checkbox"/> Metals and Alloys (8) | <input type="checkbox"/> Varnishes and Coatings (15) |

Materials used in this equipment that are intended to contact food were assessed per regulations and/or texts referenced in ANNEX 1 of this declaration. Compliance is subject to material and equipment storage, handling and usage recommended by the equipment instruction manual, and supplemental technical publications published by Graco.

The establishment of this declaration is based on the following:

- Statements of raw material suppliers
- Analysis of global migration
- Analysis of materials is subject to limitations (Listed in ANNEX 2)
- Other (Listed in ANNEX 3)

Graco Inc. will make available to the competent authorities appropriate documentation to demonstrate this compliance.

APPROVED BY:

Hans van Cranenbroek
Operations Director - EMEA

Manufactured By:
GRACO INC.
88 – 11th Avenue N.E.
Minneapolis, MN 55413
USA

Authorized representative:
GRACO DISTRIBUTION BVBA
Slakweidestraat 31
3630 Maasmechelen
Belgium

Date:

30 MARCH 2022

Part Number:

Rev:

199482

H

ANNEX 1 TO DECLARATION OF COMPLIANCE

References and Regulations Used

All Materials:

Framework Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109 EEC

Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practices for materials and articles intended to come into contact with food

Metals and Alloys:

Technical Document – Guidelines on Metals and Alloys Used as Food Contact Materials (09.03.2001)

Plastics:

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

Commission Regulation (EU) No 1282/2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

Rubber and Elastomers:

Council of Europe Committee of Ministers Resolution ResAP(2004)4 on rubber products intended to come into contact with foodstuffs

ANNEX 2 TO DECLARATION OF COMPLIANCE

Analysis of Materials Subject to Limitations

The following wetted parts and/or materials used in this product may have migration amounts above those allowed by EU or National regulations or directive under certain conditions and are therefore subject to the following limitations.

Part No	Description	Limitation
16H679	Overmold Diaphragm	Contact not to exceed 24 hours when temperatures are above 85°C. Simulants used to verify compliance: Water, 3% Acetic Acid, 10% Ethanol, 96% Ethanol (Alternative to olive oil).
108839	Diaphragm PTFE 515	Simulants used to verify compliance: Distilled Water, 10% Ethanol, 3% Acetic Acid, Rectified Olive Oil.
108639	Ball PTFE	Simulants used to verify compliance: 10% Ethanol, 3% Acetic Acid, 20% Ethanol, 50% Ethanol, Vegetable Oil.
110004	O-Ring PTFE	Simulants used to verify compliance: 10% Ethanol, 3% Acetic Acid, 20% Ethanol, 50% Ethanol, Olive Oil, DI Water.
110954	O-Ring PTFE	Simulants used to verify compliance: 10% Ethanol, 3% Acetic Acid, 20% Ethanol, 50% Ethanol, Olive Oil, DI Water.

All wetted parts and/or materials used in this product have not been tested under all conditions using all simulants. It is the responsibility of the end user to assure compliance under the specific conditions used by the end user .

ANNEX 3 TO DECLARATION OF COMPLIANCE

Other Items Used to Establish this Declaration

None

Date:

30 MARCH 2022

Part Number:

199482

Rev:

H