



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 1040, 2150, 3000, 4000 Saniforce EODD Pumps with
EO, PT, PS, or PO diaphragms, SS Seats, and PT Balls or SST Flapper checks

Configuration 2150T-E,xxxx xx x-x SS PT PT EP / 2150T-E,xxxx xx x-x SS PT PT PT,
2150T-E,xxxx xx x-x SS PT PO EP / 2150T-E,xxxx xx x-x SS PT PO PT,
Number (1040/2150/3000/4000)xx. ExxxxSSxSSPTEOxxXX or ExxxxSSxFL-EOxxXX
(1040/2150/3000/4000)xx. ExxxxSSxSSPTPOxxXX or ExxxxSSxFL-POxxXX
(1040/2150/3000/4000)xx. ExxxxSSxSSPTPSxxXX or ExxxxSSxFL-PSxxXX

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:

Revision:

199666

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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 global 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	DIAPHRAGM, HD, PTFE/EPDM,515	Contact not to exceed 24 hours for temps above 85°C. Simulants used to verify compliance: Water, 3% Acetic Acid, 10% Ethanol, 96% Ethanol (alternative to Olive Oil).
15G744	DIAPHRAGM, HD, PTFE/EPDM,1040	Contact not to exceed 24 hours for temps above 85°C. Simulants used to verify compliance: Water, 3% Acetic Acid, 10% Ethanol, 96% Ethanol (alternative to Olive Oil).
15G745	DIAPHRAGM, HD, PTFE/EPDM,1590	Contact not to exceed 24 hours for temps above 85°C. Simulants used to verify compliance: Water, 3% Acetic Acid, 10% Ethanol, 96% Ethanol (alternative to Olive Oil).
15G746	DIAPHRAGM, HD, PTFE/EPDM,2150	Contact not to exceed 24 hours for temps above 85°C. Simulants used to verify compliance: Water, 3% Acetic Acid, 10% Ethanol, 96% Ethanol (alternative to Olive Oil).
15G683	EPDM Overmold Diaphragm 1.5"	Results of migration testing of larger diaphragm of same design and material composition (15F914) apply to this diaphragm also.
15F914	EPDM Overmold Diaphragm 2"	Migration testing only done at these conditions: 5 minutes, 40°C, fatty simulants. Results at other conditions are unknown.
15H829	O-RING, 338 EPDM	End User's application R_{total} not to exceed .001 per CoE ResAP(2004)4
108639	BALL, PTFE	Simulants used to verify compliance: 10% Ethanol, 3% Acetic Acid, 20% Ethanol, 50% Ethanol, Vegetable Oil
15H831	O-RING, 338 PTFE	Simulants used to verify compliance: 10% Ethanol, 3% Acetic Acid, 20% Ethanol, 50% Ethanol, Olive Oil, DI Water

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Part No	Description	Limitation
188605	DIAPHRAGM, PTFE 1040	Simulants used to verify compliance: 3% Acetic Acid, 10% Ethanol, 50% Ethanol, Distilled Water, Rectified Olive Oil.
15K312	DIAPHRAGM, PTFE 1590	Simulants used to verify compliance: 3% Acetic Acid, 10% Ethanol, 50% Ethanol, Distilled Water, Rectified Olive Oil.
15K313	DIAPHRAGM, PTFE 2150	Simulants used to verify compliance: 3% Acetic Acid, 10% Ethanol, 50% Ethanol, Distilled Water, Rectified Olive Oil.
112088	BALL, PTFE 1040	Simulants used to verify compliance: 1.3% Acetic Acid, 2.1% Ethanol, 3.2% Ethanol, 4.5% Ethanol, Rectified Olive Oil.

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

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