



Certificate of conformity

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Romynox product label

Material Compliance

We hereby confirm that the soft parts have the following certifications which are present or tests have been performed.

- U.S. Food and Drug Administration (FDA)
 - The material meets the Code of Federal Regulations CFR21 §177.1550, Perfluorocarbon Resins of the Food and Drug Administration, FDA USA.
 - The material meets the Code of Federal Regulations CFR21 §177.2600, Elastomers of the Food and Drug Administration, FDA USA.
- EU Regulation 1935/2004 & EU Regulation 2023/2006.
The monomers used for the production are tested by EC Regulation 10/2011, amended by Regulation (EU) 2 and Regulation (EU) 1183/2012.
- USP VI Biocompatible plastics - The compound has met the requirements of the US Pharmacopeia,
 - USP Class VI - 121°C <88>
 - USP Cytotoxicity Testing <87>
- RoHS
The products are compliant with RoHS II Directive 2011/65/EU and Its Amendment (EU) 2015/86 and are free from Asbestos and Polychlorinated Biphenyls (PCB's).
- REACH
The products are compliant with REACH SVHC List 2018.



- TSE/ BSE (ADCF)
 - raw materials are not manufactured from animal or human origin.
- Free of Allergens, Melamine and Other substances
 - part are Phthalate Free
 - part are Melamine free
 - part are Nitrosamines Free

A handwritten signature in black ink, appearing to read 'R. van Grieken', written in a cursive style.

Robert van Grieken
Quality Assurance Manager



STORAGE PROCEDURES AND SHELF LIFE

ELASTOMERIC & PTFE AND FEP GASKETS, O-RINGS & DIAPHRAGMS

The shelf life of elastomeric, PTFE and FEP gaskets, O-Rings, tubing and diaphragms is dependent on many factors pertaining to their storage conditions. Products stored in their original packaging in a dry, cool environment away from direct sun light and artificial light should remain in optimal condition for 10 years. We do, however, recommend visual inspection of gaskets for discoloration, hardening and deformation

TEMPERATURE: In order to avoid certain forms of deterioration that may occur at higher temperatures, storage temperatures should be below 77F (25 C). The effects of low temperatures are not permanently damaging, but articles may stiffen more than usual.

HUMIDITY: Store in a dry environment to avoid condensation.

LIGHT: Gaskets & diaphragms should be protected from light, especially direct sunlight and strong artificial light with high ultraviolet content.

OXYGEN AND OZONE: Whenever possible, gaskets and diaphragms should be protected from circulating air, ozone is very abrasive toward rubber, storage rooms should not contain any equipment capable of generating ozone such as mercury lamps, electric motors and any other equipment that produces electrical sparks and discharge.

DEFORMATION: Whenever possible, gaskets and diaphragms should be stored in a relaxed condition free from tension, compression or other deformation.

CONTACT WITH LIQUID OR SEMI-SOLID MATERIALS: Rubber should not come in contact with liquids or semi-solid materials, especially solvents, oils and greases at any time during storage.

ROTATION OF STOCKS: Gaskets and diaphragms should remain in stores for as short of a period as possible. Therefore, articles should be issued from stores in strict rotation.