

**Romynox BV**

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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 §177.2600, Elastomers of the Food and Drug Administration, FDA USA.
- USP VI Biocompatible plastics - The compound has met the requirements of the US Pharmacopeia,
  - USP Class VI - 121°C <88>
- ISO 10993  
The products meets as per ISO 10993 part 1 for Medical Devices. This product is NOT INTENDED FOR INVASIVE USE.
- RoHS  
The products are compliant with RoHS Regulation 2015/95/EG
- TSE/ BSE (ADCF)
  - raw materials are not manufactured from animal or human origin.
  - part are Phthalate Free

The products are made of:

Silicone:  
Shelf life 5 years

  
Robert van Grieken  
Quality Assurance Manager

## STORAGE PROCEDURES AND SHELF LIFE

### SILICONE GASKETS, O-RINGS & HOSES

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The shelf life of silicone gaskets, O-Rings, tubing and hoses 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 5 years. We do, however, recommend visual inspection of gaskets for discoloration, hardening and deformation and the hydro testing of pressure rated hoses after three years.

**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 & hoses should be protected from light, especially direct sunlight and strong artificial light with high ultraviolet content.

**OXYGEN AND OZONE:** Whenever possible, gaskets and hoses 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 hoses 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 hoses should remain in stores for as short of a period as possible. Therefore, articles should be issued from stores in strict rotation.