Certificate of Conformity

Romynox BV		
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The Netherlands	VAT-nr.:	NL8206.65.009.B.01

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.

- 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>

- REACH
  The products are compliant with REACH Regulation 1907/2006/EG
  - parts are Phthalate Free

- TSE/ BSE (ADCF)
  - raw materials are not manufactured from animal or human origin.

- ISO 10993
  The products are compliant with ISO 10993 Sections 5,10,11:2009.

- 3A
  The products are compliant with 3A Sanitary Standard Class II

- EP
  The products are compliant with European Pharmacopoeia 3.1.9 ED. VII 2011;.

- BfR
  The products are compliant with BfR Recommendation XV;

The products are made of:
Platinum Cured Silicone with Stainless Steel wire reinforcement:
Romy-Flex Bright

Robert van Grieken
Quality Assurance Manager

GUIDELINES FOR CLEANING AND SANITIZING

ELASTOMERIC & PTFE HOSES

The cleaning and sanitizing suggestions set forth below are guidelines only.

It is necessary that all applicable government regulations pertaining to the cleaning and sanitizing of the hoses and hoses assemblies be followed and adhered to and which governmental regulations supersede the guideline contained herein.

The life of the hose is affected by the cleaning and sanitizing process due to the mechanical and chemical stresses which occur during the cleaning and sanitizing procedure. The service period of rubber hoses is dependent on their formulation and the environment of use which in turn is influenced by the product, process temperature, cleaning and bactericidal compounds and time of exposure. Users should frequently monitor the physical condition of the rubber hose material product contact surfaces. Such observations are necessary to determinate the actual sanitary service period of rubber hoses. It is further recommended that the rubber hose be replaced before surface imperfections or sloughing occurs. Routine replacement schedules should be established and followed.

CLEANING AND SANITIZING STEPS

1. FREQUENCY: The frequency of the cleaning and sanitizing cycle needs to be done according to the type of medium being conveyed and the contamination risk level. In principle, the cleaning and sanitizing process should be conducted on a frequent basis.

2. WASHING: Thoroughly washing the hose with hot potable water is the first step in the cleaning process. Washing with hot potable water will facilitate the cleaning of the hose but does not eliminate the need to clean the hose with the appropriate detergent followed by the disinfection of the hose. The temperature of the hot water and duration of the washing/rinsing cycle will depend upon the characteristic of the material/products being conveyed. The initial washing/rinsing with hot potable water should be completed as soon as possible after the conveyance process is completed. All residual water and residue from the initial washing/rinsing cycle must be drained away completely.

3. CLEANING/DISINFECTING: The selection of a specific detergent and of a specific disinfectant will depend on the material/products being conveyed. The recommendation of the manufacturer of the detergent and of the disinfectant should be strictly followed especially regarding concentration levels. After the cleaning of the hose with detergent followed by the rinse of it with potable water, the hose must be sterilized either with steam or with chemical solution. Steam is classified as “Physical” disinfectants: its effectiveness in eliminating bacteria and other contaminants varies according to the material/products being conveyed and the procedure employed by the users. Chemical disinfectant such as caustic soda, nitric acid, per-acetic acid, - phosphoric acid, chloroacetic acid or other acids suitable for disinfecting food hoses must be carefully selected to ensure optimal effectiveness while also assuring maximum safety and health. When selecting a particular disinfectant, it is necessary to pay strict attention to concentration levels, temperature, cycle time, etc. The type of product/material being conveyed be taken into consideration when selecting a specific disinfectant. As soon as the disinfecting treatment with chemical solutions is made, the hose must be carefully and for a sufficiently long time rinsed with potable water to eliminate any chemical residues from the disinfecting treatment.

4. PROCESS CONTROLS: The result of the cleaning and sanitizing process must be regularly checked to ensure that all contamination and residuals have been eliminated. Any non-conforming events need to be addressed in a corrective action procedure.

GUIDELINES CHART FOR CLEANING AND SANITIZING HOSES

	Medium	Hose tube	Concentration	Temperature
RINSING	Hot Water	Silicone / PTFE	-	Max 90°C
PHYSICAL DISINFECTANT	Steam	PTFE	-	Max 130°C Max 30 min
		Silicone	-	Max 135°C Max 18 min
CHEMICAL DISINFECTANT	Acid [i.e. Nitric acid]	Silicone	0,1%	Max 65°C
			2%	Max 25°C
		PTFE	0,1%	Max 85°C
			3%	Max 25°C
	Alkaline solution [i.e. Caustic soda]	Silicone	2%	Max 65°C
			4%	Max 25°C
		PTFE	2%	Max 85°C
			5%	Max 25°C
	Disinfectant [i.e. Peracetic acid]	Silicone	1%	Max 25°C
		PTFE		Max 40°C

The life of the hose is affected by the cleaning and sanitizing process due to the mechanical and chemical stresses which occur during the cleaning and sanitizing procedure. The service life of rubber hoses is directly dependent on frequency and time of exposure to PHYSICAL and CHEMICAL disinfectants. Users should frequently monitor the physical condition of the rubber hose material product contact surfaces. Such observations are necessary to determinate the actual sanitary service period of rubber hoses.

The present tabulation is based on tests and on generally available sources, and believed to be reliable. However, must be used as a guidance only since it does not take in consideration all variable that may be encountered in actual use such as and not limited to duration of exposure and stability of the fluid and possible contamination.

STORAGE PROCEDURES AND SHELF LIFE

ELASTOMERIC & PTFE HOSES

The shelf life of elastomeric and PTFE 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 10 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: Hoses should be protected from light, especially direct sunlight and strong artificial light with high ultraviolet content.

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