



## Certificate of conformity

**Romynox BV**

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**Romynox product label**

## Material Compliance

We hereby confirm that the EPDM Sleeve of the Iris Valve 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>
- EU Regulation 1935/2004  
The POM used for the production is in compliance with EC Regulation 10/2011 and his amendments, and including the Regulation (EU 1935/2004).
- TSE/ BSE (ADCF)  
Raw materials are not manufactured from animal or human origin.
- RoHS - Restriction of Hazardous Substances  
The products are compliant with RoHS Regulation 2015/95/EG
- REACH - Registration, Evaluation. Authorisation and Restriction of Chemicals  
The products are compliant with REACH Regulation 1907/2006/EG

The products are made of:  
Iris Sleeve: EPDM (White)

Robert van Grieken  
Quality Assurance Manager