# Declaration of conformity


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


| **Romynox product label** |
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# 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 §177.1500, Nylon resins, FDA USA.

- USP VI Biocompatible plastics - The compound has met the requirements of the US Pharmacopeia,
  - USP Class VI <88>

- ISO 10993
  The products meets as per ISO 10993 -5 (Cytotoxicity) and -11 (Systemic toxicity) regulatory testing requirement.

- RoHS
  The products are compliant with the requirements of the Directive (EU) 2015/863 (RoHS 3) amending Annex II to directive 2011/65/EU (RoHS 2)

- REACH
  The products does not contain any of the Substances of Very High Concern listed in the REACH 'Candidate List' (published in accordance with Article 59(10) of the REACH Regulation) as last amended on 8th July 2021 above the limit of 0.1%.
  The products does not contain any of the substances subject to authorization as listed on the Annex XIV of Regulation (EC) N° 1907/2006 as last amended on 6th February 2020 (Regulation (EU) 2020/171).

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

The products are made of:
Zytel® FGFE5171 NC010C

Robert van Grieken
Quality Assurance Manager