



European  
Sealing  
Association e.V.

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## Regulation (EC) No 1935/2004, Article 16 – Declaration of compliance for materials and articles intended to come into contact with food

Note: This Position Paper is intended only as a guide and offers only an overview of the declaration of compliance in accordance with Regulation EC No 1935/2004.

### Underlying Principle of EC 1935/2004

**Article 3** states that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities, which could endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.

**Article 16** of the Regulation necessitates a written declaration of compliance only if specific measures are required for particular materials and articles. The specific measures may be adopted or amended and are laid out in **Article 5** and the materials affected are listed in **Annex 1** of the Regulation.

In relation to Mechanical Seals the possible material groups as listed in Annex 1 are:

- |                                    |   |
|------------------------------------|---|
| 3. Ceramics (Directive 84/500/EEC) | Material type not used in Mechanical Seals  |
| 5. Rubbers *                       | Elastomers: To date there are no specific measures in place therefore there is no requirement to provide a written declaration of compliance *1 |
| 8. Metals and alloys               | To date there are no specific measures in place therefore there is no requirement to provide a written declaration of compliance *2             |
| 13. Silicones                      | Seldom in mechanical seals.   |

In the absence of specific measures, Member States (EU) may retain or adopt national provisions providing they comply with the European Treaty.

\*1 In the case of Rubber materials Article 16 of EC 1935/2004 allows for the member countries to create specific measures/tests for that must be passed in order to gain approval for food contact within their nation. As an example, in

Germany, the Federal Institute for Risk Assessment (BfR) system is widely followed and well respected for proving rubber food contact credentials in the EU. BfR recommendation XXI covers natural/synthetic rubber. In the absence of any National approval system the guidelines of the FDA Code of Federal Regulations are sometimes referred to.

\*2 Metals that are used in the industry include stainless steel in particular. In the opinion of the association, stainless steel can be regarded as uncritical in this context and as meeting the latest technological standards provided that it fulfils the current specifications with regard to composition etc. and is not contaminated by unwanted components.

## **Overview**

For materials and articles for which no specific measures have been adopted a written declaration of compliance within the meaning of the Regulation EC 1935/2004 does not need to be submitted.

References:

Regulation EC 1935/2004:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&qid=1466076155949&from=en>

VDMA Position Paper: Regulation EC 1935/2004 Article 16. Published 22/5/2013

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