Markgröningen, 01/09/2025

Declaration of conformity for operating parts and standard elements with Hygienic USIT® seal and shim washers

Dear Sir/Madam,

we hereby declare that the **operating parts and standard elements** with **Hygienic USIT® seal and shim washers** from the **Hygienic** product range are suitable for contact with foodstuffs.

The **stainless steel materials** used, 1.4401 and 1.4404, meet the criteria of ANSI/NSF 51 (para. 7.1) and are classified as “GRAS” (Generally Recognized As Safe) according to the FDA (Food and Drug Administration) Title 21 of the CFR (Code of Federal Regulations). In addition, they comply with EU general requirements for food contact materials according to framework regulation (EC) No. 1935/2004. Stainless steel materials are generally considered to be free of animal derivative ingredients (ADI) and therefore do not contain any substances that could trigger BSE/TSE.

The **elastomer materials** used, 75 EPDM 295-black (replacement for 70 EPDM 291-black), 70 EPDM 291-black, 70 EPDM 253815-white and 75 Fluoroprene® XP 45-blue, meet the required purity criteria according to FDA (Food and Drug Administration) Title 21 of the CFR (Code of Federal Regulations) in §177.2600 as well as the general requirements for materials in contact with foodstuffs according to the framework regulations (EC) No. 1935/2004 and 2023/2006 (GMP). The materials are considered to be free of ADI and therefore do not contain any substances that could trigger BSE/TSE.

Furthermore, 75 EPDM 295-black and 70 EPDM 291-black are certified according to 3-A® Sanitary Standards Class II. Both materials, as well as 70 EPDM 253815-white meet the requirements of the United States Pharmacopeia (USP) and have passed the biological tests for plastics USP Chapter <87> & <88> Class VI.

This declaration is based on analysis results or material certificates provided by sub-suppliers, declarations from sub-suppliers of any kind and/or laboratory test results of the raw materials used to manufacture the product.

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