Hygienic USIT[®] Technical Information



For hygienic sealing in and at the product area

With its highly reliable sealing and design that is compliant with hygiene requirements, the Hygienic USIT[®] seal and shim washer is setting new standards for cleanliness in the process industry. Many manufacturers of machinery and systems for the food and pharmaceutical industries often use standard shim washers or 0-rings for screw connections in or on the product chamber. These are not EHEDG-compliant, however, as contamination and biofilms in the form of bacteria colonies and corrosion can form under the screw head, preventing the design from achieving maximum hygiene standards.

The metallic shim washer with a fixed sealing ring made from 75 EPDM 295 (black) or 70 EPDM 253815 (white) provides a secure, cavity-free seal. The Hygienic USIT[®] seal and shim washer, made from the fluorinated premium compound Fluoroprene[®] XP 45, is suitable for applications involving particularly aggressive CIP/SIP cleaning temperatures, high steam sterilisation temperatures and process media containing grease. This material has an even larger operating temperature range and is resistant to polar and non-polar media as well as flavouring substances.

Approvals such as FDA, EU1935/2004 and USP Class VI (121°C), plus EHEDG certification, confirm that the Hygienic USIT[®] washer represents the ideal choice for hygienically demanding applications in the food, beverage and pharmaceutical industries.

The EHEDG certificate is only valid when a specifically matched hexagon head bolt K1492 or cap nut K1493 is used.

Material	Colour	Conformity/Approvals	Temperature range	Others
75 EPDM 295	black	- FDA 21 CFR 177.2600 - 3-A® SANITARY STANDARDS CLASS II - EU (VO) 1935/2004 AND 2023/2006 - USP CH. 87 AND CH. 88 – CLASS VI – 121 °C (250 °F) - BFR XXI, Kat 4	-50 °C to +150 °C	- ADI free
70 EPDM 253815	white	- FDA 21 CFR 177.2600 - EU (VO) 1935/2004 and 2023/2006 - USP Ch. 87 and Ch. 88 – Class VI – 121 °C (250 °F) - BFR XXI, Kat 4 - BPA/Phthalat	-40 °C to +150 °C	- ADI free
75 FLUOROPRENE ® XP 45	blue	- FDA 21 CFR 177.2600 - EU (V0) 1935/2004 AND 2023/2006 - 3-A® Sanitary Standards Class I	-15 °C to +200 °C	- ADI free







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Screw connection according to Hygienic DESIGN

The Hygienic USIT[®] is a further development of the conventional standard Usit rings. It ensures reliable hygienic sealing of the screw head. It also allows easy CIP (Cleaning in Place), WIP (Washing in Place) or SIP (Sterilization in Place) without having to take the system apart.

These special screw heads have been developed according to DIN EN 1665 for areas or aseptic isolators in contact with the product. This combination prevents the medium from getting under the screw head. This eliminates the risk of contamination and formation of microfilms.

By a special production process, hygienic obtains a surface roughness of Ra $<0.8~\mu m.$ This eliminates any dents or sharp burrs on the collar.

In addition, screws and cap nuts with collar are polished to a high gloss. To fasten them consistently in accordance with Hygienic DESIGN, Hygienic has developed box nuts and associated protective inserts. They do not damage the screw when tightening.

For screw connections outside the product area, standard hexagon bolts with flange according to DIN EN 1665 are suitable. However, they do not meet the Hygienic DESIGN requirements regarding optimum cleanability. They are therefore not suitable for use in product contact areas.

The bond is available in the dimensions M4, M5, M6, M8, M10, M12 and M16.

Values to the customer

- Cavity-free solution
- Prevents microbial contamination
- Replaces inflexible welding solution
- Clearances/approvals for food and pharmaceutical industry
- No tooling costs for standard parts
- Cleaning with the CIP, SIP, WIP, COP and WOP processes



Cap nuts with collar Material: 1.4404 Surface high-gloss polished with up to Ra < 0,8 micron

Freudenberg Hygienic USIT® washer Material: Elastomer made of 75 EPDM 295, 70 EPDM 253815, or 75 Fluoroprene® XP 45 Washer made of 1.4404

Hexagon bolt with collar Material: 1.4404 Surface high-gloss polished with up to Ra < 0,8 micron

