

Declaration of Conformity FDA

Area of application: GYLON® materials, GYLON EPIX®, GYLON BIO-LINE® made of GYLON® Blue Style 3504, GYLON BIO-LINE® PLUS made of GYLON® Style 3522/3527 and GYLON® Style 3505 (which simply is unbranded GYLON® Blue Style 3504).

GYLON® Fawn Style 3500, GYLON® Standard Style 3501-E, GYLON EPIX® Standard Style 3501-E EPX and GYLON® White Style 3510, GYLON EPIX® White Style 3510 EPX, comply with FDA regulation 21CFR177.1550. They meet ingredient and extract requirements. The fillers are also acceptable under 21CFR177.2600 and coloring agents (where used) under 21CFR178.3297. The branding ink complies with 21CFR175.300. GYLON® Fawn Style 3500 has USDA approval for direct contact in meat and poultry applications.

GYLON® Blue Style 3504, GYLON EPIX® Blue Style 3504 EPX, GYLON® Style 3506 (no pigment), GYLON® ENVELON® Style 3565, GYLON® Style 3505, comply with FDA regulation 21CFR177.1550. They meet the ingredient and extract requirements. The filler is listed in the Food Chemicals Codex (FCC 3rd Edition) and is considered GRAS (generally recognized as safe – 21CFR170.30). The branding ink complies with 21CFR175.300. The pigment is approved for use in contact with food under 21 CFR 178.3297.

GYLON® Soft Style 3545 is conform with FDA regulations 21CFR177.1550, 21CFR182.1, 21CFR182.1217, and 21CFR175.300 for its ingredients. The amount of extractables can be higher than 21CFR177.1550 they meet the ingredients and extract requirements. The branding ink complies with 21CFR175.300.

GYLON® Style 3522 / 3527 does comply with FDA regulation 21CFR177.1550 with all ingredients.

The resin used in Style 3535 PTFE Joint Sealant comply with FDA regulation 21CFR177.1550. The adhesive tape used to hold the joint sealant in place meets 21CFR175.105.

Products made of GYLON® are free of Animal derivative Ingredients (ADI-free), free of Silicone and free of Phthalates (individual declaration available, including other GYLON® Styles).

Products made of GYLON® Blue Style 3504, GYLON® White Style 3510 as well as GYLON® Style 3522/3527 in addition to above mentioned, are also meeting following specifications:

- **EC 1935/2004, EC 10/2011** (GYLON® White Style 3510, GYLON® Blue Style 3504, GYLON® Style 3522) request within ordering process is needed for full traceability
- **USP class VI** and in addition to class VI chapters: 31, 87, 88, 281 & 661
- **Belgaqua** (this approved Hydrocheck test only is available for GYLON® Blue Style 3504)
- **NSF 61** (Approved American National Standard for drinking water systems only is available for unbranded GYLON Style 3504 which then automatically becomes GYLON® Style 3505)
- **ABS** (Committee of operational safety)
- **IEC/TS 60079-32** (Approved Avoidance of electrostatical potential or charge transfer)
- **BAM** (free of reactivity for usage in gaseous or liquid Oxygen and H2 Service –H2 only for GYLON® 3504 and GYLON® 3510-)

Other certificates and declarations are available on request.

This document has no date of expiration.

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