

Letter of Conformance ANIMAL DERIVATES INGREDIENTS (ADI)

Area of application: GYLON[®] materials, GYLON EPIX[®], GYLON BIO-LINE[®] made of GYLON[®] 3504 blue, GYLON BIO-ASEPT[®], GYLON BIO-ECO[®], GYLON BIO-PRO[®], GYLON BIO-LINE[®] PLUS made of GYLON[®] Style 3522.

We hereby confirm that formed or cut components and sheets, made for the purpose of sealing, regarding the materials of above mentioned product lines and

GYLON[®]

in general, are conform to the guidelines of risk minimizing of virus transmission concerning TSE (Transmissible spongiform encephalopathy) from an animal source caused by human and animal medicines (EMEA/410/01 Rev.3 – March 2011). This guideline is accepted by Committee for Proprietary Medicinical Products – CPMP and Committee for Veterinary Medicinical Products – CVMP.

TSE diseases in Example include bovine spongiform encephalopathy (BSE) in cattle, SCRAPIE in sheep and goats, chronic wasting desease (CWD) in cervids like deer and elk, as well as different forms of Creutzfeldt-Jakob Disease (CJD) in humans.

This guideline is announced in the gazette C24 of the European Union at the 28_{th} January 2004 and C73 at 05_{th} March 2011.

The mentioned materials are fully synthetic materials and free of products from animal sources.

All materials have to be disposed in accordance to local regulations. This document has no expiring date.

Neuss, 10. November 2022 Ralf Kulessa, Senior Application Engineer

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