Sealing for a safer and greener tomorrow

26062023

Declaration of Compliance Food and pharmaceutical physiological harmless

We hereby declare that the ePTFE sealing material **TEADIT 24BB** is in compliance with the following directives, standards and regulations, amendments included.

1. EC Framework Regulation 1935/2004, EU No. 2023/2006, EU No 10/2011, LFGB

The tested sample **meets the requirements** of LFGB and Regulation (EC) No. 1935/2004 in the tested items. Stability criteria according to Regulation (EU) No. 10/2011 are met. Food additives, according to Regulation EU 231/2012, are <u>not used</u> for the production.

The investigated sample was tested at 100°C for Simulant A and B and at 175°C for Simulant D2.

SGS Test-report no. 6138760

Zusammenfassung der Analysenergebnisse / Summary of results

| Prüfung / Test | Ergebnis / Result |
|---|-------------------|
| Sensorische Prüfung / sensory test | bestanden / pass |
| Globalmigration / overall migration | bestanden / pass |
| Spezifische Migration von Metallen nach Verordnung (EU) Nr. 10/2011 / specific migration of metals according to Regulation (EU) No 10/2011 | bestanden / pass |
| Schwermetalle im Migrat (Finnland) / heavy metals migration (Finland) | bestanden / pass |
| Farblässigkeit / colour release | bestanden / pass |
| Spezifische Migration von primären aromatischen Aminen / specific migration of | bestanden / pass |
| primary aromatic amines | |
| PAK / PAH | bestanden / pass |
| Spezifische Migration von Perfluormethyl-perfluorvinylether (CAS-Nr. 1187-93-5) / specific migration of perfluoromethyl perfluorovinyl ether (CAS no. 1187-93-5)* | bestanden / pass |
| Weichmacher / Plasticizers | bestanden / pass |
| Bisphenol A | bestanden / pass |
| Kurzkettige Chlorparaffine (SCCP) / Short chain chlorinated paraffins (SCCP) | bestanden / pass |
| Perfluorierte Verbindungen (PFC) / perfluorinated compounds (PFC) | bestanden / pass |

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TEADIT International Produktions GmbH

Europostrasse 12, 6322 Kirchbichl, Austria Tel. +43 5332 74000 Fax +43 5332 74000-120 e-Mail: austria@teadit.eu www.teadit.eu UniCredit Bank Austria in Woergl, Austria IBAN: AT34 1100 0048 9323 6200 (EURO Konto/Account) IBAN: AT04 1200 0048 9323 6202 (USD Konto/Account) BIC/Swift-Address BKAUATWW Sparkasse Kufstein Tiroler Sparkasse IBAN: AT73 2050 6077 0014 9912 (EURO Konto/Account) BIC/Swift-Address: SPKUAT22XXX



ARA-Lizenz-Nr.: 4223 - UID-Nr. ATU31891209 - Rechtsform: GmbH - Sitz: 6322 Kirchbichl, FN 52702d, Handelsgericht Innsbruck Es gelten unsere allgemeinen Geschäftsbedingungen / Our Genereal Terms of Business apply

2. U.S. Regulations 21 CFR 177.1550

Based on the screening results, including the analytical tolerance, the investigated sample is in compliance with the limits for the "Total extractives" and the "Fluoride extractives" according to 21 CFR 177.1550 "Perfluorocarbon resins".

SGS Test-report no. 6379061

Zusammenfassung der Analysenergebnisse / Summary of results

| Prüfung / Test | Ergebnis / Result |
|--|-------------------|
| FDA 21§ CFR 177.1550 extrahierbare Anteile / FDA 21§ CFR 177.1550 extractable fraction | bestanden / pass |
| FDA 21§ CFR 177.1550 extrahierbares Fluor / FDA 21§ CFR 177.1550 determination of fluorine | bestanden / pass |

3. ADI/BSE/TSE

We do not use animal derived ingredients at production. The product is free of BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

This declaration of compliance is valid for the product delivered by us and as specified above. The information included in this document is valid for the stated revision versions and dates and/or until this document is superseded.

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TEADIT International Produktions GmbH Europastrasse 12, 6322 Kirchbichl, Austria

Tel. +43 5332 74000 Fax +43 5332 74000-120 e-Mail: austria@teadit.eu www.teadit.eu

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