

Declaration of Compliance

Food and pharmaceutical physiological harmless - BIOCOMPATIBILITY

We hereby declare that the ePTFE sealing material **TEADIT 30SH** 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 not used for the production.

The investigated sample was analyzed under standard test condition OM-7, with food simulant A and B at 4h/100°C and with food simulant D2 at 2h/175°C, each at a ratio of 6 dm²/L, respectively. This shows that the overall migration limit is met for all types of food.

SGS Test-report no. 6158638

Zusammenfassung der Analyseergebnisse / 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 primary aromatic amines	bestanden / pass
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



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. 6158253

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. USP Class VI - BIOCOMPATIBILITY

The material sample used for implantation tests met the requirements of the USP Class VI Plastic up to a **temperature of 121 ± 2 °C**.

4. 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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