

## DECLARATION OF CONFORMITY

in accordance with  
DIN EN ISO/IEC 17050

Date: 5 April 2022  
Phone: +41 44 306 62 59  
Issuer: GAAX

### Declaration subject:

Material description:

### PERTEC® CIP FKM 75.501-04

The material described above meets the requirements stipulated in the following guidelines/standards:

#### Food & Beverage

	<u>Expiry date or unlimited</u>
• FDA CFR 21 - 177.2600 a) – f)	unlimited
• KIWA NSF/ANSI 51 formulation	regularly attested
• 3-A Sanitary Standard N° 18-03 Class I	unlimited
• EC 1935/2004 (excl. article 15) and EC Regulation 2023/2006 (GMP)	unlimited
• BfR XXI Category 4	unlimited
• LFGB §30/31	unlimited
• French Arrêté 05/08/2020 (Migration test)	unlimited
• D.M. 21/03/1973 (Migration test)	unlimited
• Dlgs. 25.01.1992 n.108 Art.2 (ex. DPR 777/82 art 2)- complies with Arsenic content limits	unlimited
• BNIC (Bureau National Interprofessionnel de Cognac)	unlimited
• SR 817.023.21	unlimited
• GB 4806.11-2016 (Migration test)	unlimited
• Mercosur GMC/RES N° 54/97 (Migration test)	unlimited

#### Medical / Pharma

• USP Class VI, Chapter <87> (In Vitro) and Chapter <88> (In Vivo) - 121°C	unlimited
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**Other declarations (declaration revision date: January 17, 2022)**

The following statement is based on the current state of our knowledge and is valid from the declaration revision date until the document is superseded. The declaration is valid until the Regulations and Directives are amended. Due to possible changes in the underlying Regulations and Directives, it is not guarantee that the status of this document will remain unchanged. It will be renewed in all case where the declaration is no longer ensured.

We hereby declare that our compound complies with the Regulations and Directives as below:

- REACH (EC) No 1907/2006 and amendments, Annex XIV, Annex XVII and art. 59 (SVHC list as of January 17, 2022)
- RoHS 2011/65/EU & 2015/863/EU
  
- PAK Cat. 1 (AfPS GS 2019:01)
- ADI free (free of Animal Derived Ingredients) resp. TSE/BSE related substances
- BPA free, Bisphenol A free
- DEHP, free of phthalates
- Natural rubber latex free
  
- US EPA (United States Environmental Protection Agency), Toxic Substances Control Act (TSCA) section 6(h) resp. decaBDE / PIP 3:1 / 2,4,6-TTBP / HCBd / PCTP.

**Angst + Pfister Group Engineering**

Valerie Thurau, PhD



A.Gabor

Zurich, 5 April 2022

(Place and date of issuance)

Approval and Regulatory Affairs Manager

Engineering Data Administrator

(Name and signature or equivalent authentication of authorized persons)