PHACOTEC
PRODUKT-SERVICE GMBH
HEEGBARG 14
22391 HAMBURG
DEUTSCHLAND

Declaration of Conformity (PPWR)

Series Anglocap Pharma-Tech

Version 26_252_EN
Date 16.06.2026

Declaration of Compliance pursuant to Article 39 in conjunction with Articles 5–12 of Regulation (EU) 2025/40

(1) Identification of the packaging unit
This declaration applies to the following article numbers, including all colour variants and all article numbers derived therefrom 502095

(2) Responsible company
• Manufacturer: Pharma-Tech A/S, Messingvej 23, 8940 Randers SV (DK)
• Distributor: PHACOTEC Produkt-Service GmbH, Heegbarg 14, 22391 Hamburg (DE)

(3) The manufacturer (2) bears sole responsibility for issuing this declaration of conformity. The distributor acts solely as an economic operator within the supply chain.

(4) Subject of the declaration
Product line Anglocap Pharma-Tech made of PE, intended for use as primary packaging (single-use) for medicinal products, food supplements, pharmaceutical and related products.

The material used and the intended use are, in principle, identical within the product series, regardless of the nominal or filling volume. The technical documentation in accordance with Article 39 of the PPWR is maintained by the manufacturer and made available to the competent market surveillance authorities upon request.

(5) Product and regulatory compliance
The producer (2) confirms that the product referred to under section (4) complies with the applicable requirements of Regulation (EU) 2025/40. This includes, in particular, compliance with the following provisions:
• Article 5 (Minimisation of Weight and Volume): The packaging has been designed in accordance with its intended function in such a way that its weight and volume are limited to the minimum necessary to ensure product protection, product safety, stability and usability.
• Article 6 (Recyclability): The packaging consists of PE monomaterial and is suitable for material recycling within existing plastic recycling systems. The classification is subject to future delegated acts and harmonised assessment methodologies to be adopted by the European Commission.
• Article 7 (Recycled Content): The packaging does not contain intentionally added post-consumer recycled material. The requirements applicable to this packaging under Article 7 are fulfilled in accordance with the relevant transitional provisions and implementing measures in force from time to time.
• Article 9 (Substance Restrictions): To the best of the producer's knowledge, no intentionally added per• and polyfluoroalkyl substances (PFAS) are used in the manufacture of the packaging. The packaging complies with the concentration limits for lead, cadmium, mercury and hexavalent chromium laid down in Regulation (EU) 2025/40. To the best of the producer's current knowledge, the raw materials and additives used do not contain intentionally added Bisphenol A (BPA), other bisphenols or bisphenol derivatives within the meaning of Regulation (EU) 2024/3190. Furthermore, the raw materials used comply with the requirements of Regulation (EC) No. 1907/2006 (REACH). Based on the information available to the producer, the product does not contain substances included in the current Candidate List of Substances of Very High Concern (SVHC) pursuant to Article 59 of REACH in concentrations exceeding 0.1% by weight (w/w). In addition, the raw materials used comply with the applicable food-contact and pharmaceutical requirements.
• Article 12 (Labelling): The packaging is supplied in accordance with the applicable labelling requirements of Regulation (EU) 2025/40. Where transitional provisions apply or implementing acts of the European Commission have not yet been published for the relevant packaging category, implementation will take place once such provisions enter into force.

(6) Information on Standards / Specifications
The producer (2) confirms compliance with the food-contact requirements applicable to the packaging concerned, in particular:
• Regulation (EC) No. 1935/2004

PHACOTEC
PRODUKT-SERVICE GMBH
HEEGBARG 14
22391 HAMBURG
DEUTSCHLAND

- Regulation (EU) No. 10/2011
- Regulation (EC) No. 2023/2006

Further details regarding food-contact materials, conditions of use, migration requirements and, where applicable, substances subject to specific migration limits are set out in the separate Declaration of Compliance for food contact materials relating to product series Anglocap Pharma-Tech.

(7) Declaration
The distributor (2) confirms that the above information has been prepared to the best of their knowledge on the basis of the available information, specifications, supplier declarations and technical documentation provided by the manufacturer (2).

This document was created digitally based on information provided by the responsible company (1) and is valid without a signature.

PHACOTEC
PRODUKT-SERVICE GMBH
HEEGBARG 14
22391 HAMBURG
DEUTSCHLAND

Supplementary Notes and Explanations regarding Regulation (EU) 2025/40

(1) General
The present PPWR compliance assessment is based on manufacturer information, raw material specifications, supplier declarations, test reports and other technical documentation available at the time of document preparation.
Unless expressly stated otherwise, the information has not been independently verified by the distributor.

(2) Technical Documentation
The technical documentation required under Article 39 of Regulation (EU) 2025/40 is maintained by the respective producer or manufacturer.
Access to complete technical documentation may be restricted due to trade secrets and confidential business information.

(3) Product Families and Material Groups
Manufacturer declarations, technical assessments and compliance evaluations are generally based on material families, product groups, formulations, material/colour combinations or worst-case evaluations.
Accordingly, such documentation generally applies to all covered article variants, provided that material composition, manufacturing process and intended use remain identical.

(4) Recyclability (Article 6)
The recyclability assessment is based on the legal requirements, manufacturer information and recognised evaluation methods available at the time of document preparation.
Should the European Commission publish binding harmonised assessment methodologies or delegated acts in the future, reassessment may become necessary.

(5) Recycled Content (Article 7)
Statements regarding recycled content are based on manufacturer information and available raw material documentation.
Unless expressly stated otherwise, no independent material analyses have been performed to determine recycled content.

(6) PFAS
Statements regarding PFAS are based on manufacturer and supplier declarations as well as available raw material specifications.
Analytical testing for individual PFAS substances, Total Fluorine (TF), Total Organic Fluorine (TOF) or comparable screening methods is only available where such testing has been expressly performed by the respective manufacturer or an accredited laboratory.

(7) Bisphenols
Statements regarding Bisphenol A (BPA), other bisphenols and bisphenol derivatives are based on manufacturer and supplier declarations as well as available raw material information.
Unless otherwise documented, no independent analytical testing for BPA, BPF, BPS or other bisphenol compounds has been performed.

(8) REACH and SVHC
The assessment regarding Regulation (EC) No. 1907/2006 (REACH) and the Candidate List of Substances of Very High Concern (SVHC) is based on the manufacturer information available at the time of document preparation.
Updates to the Candidate List may require an update of the underlying manufacturer declarations.

(9) Heavy Metals
Statements regarding lead, cadmium, mercury and hexavalent chromium are generally based on raw material approvals, supplier declarations, material specifications or manufacturer test reports.
Product-specific laboratory analyses are generally not available for each individual article number.

(10) Substance Testing and Product Families
Analytical testing regarding PFAS, heavy metals, migration limits or other substance restrictions is generally performed by manufacturers on material, formulation, colour or product-family level.
Separate testing for each individual article number, colour variant or production batch is generally not performed unless expressly agreed otherwise.

(11) Labelling (Article 12)
Where transitional provisions, guidance documents, implementing acts or technical specifications issued by the European Commission are still pending for specific packaging categories, implementation will take place once such requirements enter into force.

(12) Basis of Documentation
The present assessment has been prepared on the basis of manufacturer information available at the time of issue.
Updated manufacturer documentation or changes in legal requirements may require revision of the assessment.

(13) Disclaimer
This annex is provided for information purposes only.
Only the current declarations, technical documentation and compliance evidence issued by the respective producer or manufacturer shall be considered binding.
In the event of discrepancies, the original manufacturer documentation shall prevail.