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VAT ID FI07084446

DECLARATION OF CONFORMITY (DoC)

1. Company

Hutek Oy, Tiilitie 1, FI-15560 Nastola, FINLAND. VAT ID FI07084446.

2. Product Description

Hutek Oy manufactures NOVOBOX and NOVOBIB food contact packaging using virgin plastic materials including PE/EVOH/PE, LDPE, LLDPE, metallised PET (MET.PET), PE and PP. The products consist of multilayer films, glands and closures forming the inner and outer components of the packaging system.

This Declaration of Conformity applies to NOVOBOX and NOVOBIB products manufactured by Hutek Oy.

This certificate applies to the following NOVOBOX and NOVIBIB products:
Products made from LDPE and LLDPE films
1001-1006, 1008-1009, 1011-1013, 1024, 1038
1107, 1110, 1113, 1125
1207
1407, 1422-1424, 1429, 1438, 1453
1505, 1580-1581

Products made from EVOH barrier films
1007, 1010, 1014, 1019, 1022-1023, 1026-1031, 1036
1103-1106, 1108-1109, 1111-1112, 1115-1124
1204-1206, 1209-1211
1301-1305, 1307-1308, 1310, 1312-1319, 1322-1323, 1328-1332
1401-1406, 1409-1410, 1412-1414, 1416-1421, 1425-1428, 1430-1431, 1439-1440, 1442, 1444-1445,
1449-1452, 1454-1455, 1458, 1461-1462, 1467, 1481-1482
1501-1504, 1506-1508, 1511-1514, 1516-1517, 1521, 1523-1533, 1535-1539, 1542-1545, 1582
1601-1602, 1613

Products made from metallized films
1017-1018, 1021, 1032-1034
1208
1306, 1309, 1327
1415, 1443, 1456-1457, 1463, 1470, 1472
1509,1515

As the manufacturer of food contact packaging materials, Hutek Oy bases this Declaration of Conformity on information currently available, including supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures.

3. General

Applicable EU Legislation

The materials and articles covered by this Declaration of Conformity are manufactured and assessed in accordance with the applicable requirements of European Union legislation on materials and articles intended to come into contact with food. Where applicable, the following regulations and legal acts have been taken into consideration:

- Regulation (EC) **No 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.
- Commission Regulation (EU) **No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food, including all applicable amendments.
- Commission Regulation (EC) **No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, including applicable amendments.

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- Commission Regulation (EC) **No 1895/2005** of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, where applicable.
- Commission Regulation (EU) **2024/3190** on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonized classification for specific hazardous properties in materials and articles intended to come into contact with food, where applicable.
- Regulation (EU) **2022/1616** on recycled plastic materials and articles intended to come into contact with food, as amended by Commission Regulation (EU) **2025/351**, where applicable.
- Regulation (EC) **No 1907/2006** (REACH) on the registration, evaluation, authorisation and restriction of chemicals, where applicable.
- Regulation (EU) **2025/40** on packaging and packaging waste (PPWR), amending Regulation (EU) **2019/1020** and Directive (EU) **2019/904** and repealing Directive **94/62/EC**, where applicable.

Where relevant, compliance is based on information provided by raw material suppliers, internal assessments, and applicable supporting documentation. This declaration does not replace the responsibility of the user of the final article to verify compliance of the finished product under its actual and intended conditions of use.

Compliance with Non-EU Regulations
NOVOBOX and NOVOBIB products have been assessed, where applicable, for compliance with selected non-EU legislation related to materials and articles intended to come into contact with food. This assessment is based on information currently available to us, including information provided by raw material suppliers, and does not replace the responsibility of the user of the final article to ensure compliance under the actual conditions of use and applicable local requirements.

United States (USA):
U.S. Food and Drug Administration (FDA), Code of Federal Regulations, **Title 21, §177.1520** (Olefin polymers), as amended

China:
GB 4806.6-2016 National Food Safety Standard – Plastic Resins for Food Contact
GB 9685-2022 National Food Safety Standard – Use of Additives in Food Contact Materials and Articles

Switzerland:
SR 817.0 Federal Law on Foodstuffs and Consumer Goods
SR 817.02 Ordinance on Foodstuffs and Consumer Goods
SR 817.023.21 Ordinance of the DFI on Materials and Articles Intended to Come into Contact with Food

Compliance Assessment
Compliance with applicable legislation governing food contact materials and packaging is ensured through documented raw material approval, supplier qualification, supplier Declarations of Compliance, relevant technical documentation, specification management, documented change control and periodic review of supplier documentation within our ISO 22000 Food Safety Management System.

Raw materials are evaluated against applicable regulatory requirements before approval for use in production. Compliance is maintained through documented supplier approval procedures, specification management, change control and periodic review of supplier documentation to ensure continued conformity with applicable legislation.

Hutek Oy does not maintain routine analytical testing programmes for all raw materials, as the conformity assessment of food contact materials is primarily based on supplier Declarations of Compliance, relevant technical documentation, applicable regulatory requirements and our documented supplier approval process.

Where required by applicable legislation, including Regulation (EU) No 10/2011, verification of the compliance of the final packaging under its intended conditions of use remains the responsibility of the user of the final article, since migration behaviour depends on the packaged food, contact time, temperature and other reasonably foreseeable conditions of use, which are not known to Hutek Oy as the packaging material manufacturer.

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General Statement
This Declaration of Conformity addresses the applicable legal requirements relevant to Hutek Oy as the manufacturer of food contact packaging materials. Compliance of the final packaged food product under its actual and intended conditions of use remains the responsibility of the user of the final article.

4. Compliance with overall migration limit (OML)

Based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures, the films, glands and closures used in NOVOBOX and NOVOBIB products are considered to comply with the overall migration requirements of Commission Regulation (EU) No 10/2011.

Overall migration is not expected to exceed the Overall Migration Limit (OML) of 10 mg/dm², assessed using the conventional surface area to food mass ratio of 6 dm²/kg, as specified in Regulation (EU) No 10/2011. Where applicable, food simulants have been selected in accordance with Annex III of the Regulation.

Where required by Regulation (EU) No 10/2011, verification of overall migration compliance of the final packaging under its intended conditions of use shall be carried out by the user of the final article using appropriate food simulants, contact times and temperatures corresponding to the intended use.

5. Specific Migration Limit (SML)

Monomers and additives used in the manufacture of the raw materials, for which Specific Migration Limits (SMLs) have been established under Commission Regulation (EU) No 10/2011 and which are listed in Annexes I and II thereof, are considered to comply, based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures.

Where applicable, the assessment is supported by:
• supplier Declarations of Compliance;
• compositional information provided by approved raw material suppliers;
• migration modelling; and/or
• other technical evaluations carried out in accordance with the principles set out in Annex V of Commission Regulation (EU) No 10/2011.

Based on the available information, the migration of the relevant monomers and additives is not expected to exceed the applicable Specific Migration Limits (SMLs) under the intended conditions of use covered by the supplier documentation.

CAS numbers and substance identification are based on the information provided by our approved raw material suppliers.

For the purpose of this assessment, the conventional surface area to food mass ratio of 6 dm²/kg, as specified in Commission Regulation (EU) No 10/2011, has been applied.

Specific Migration Limits (SMLs)
Where applicable, the following Specific Migration Limits (SMLs) apply:

Monomers
EU Reference No. 22660
Specific Migration Limit (SML) 15 mg/kg food

Additives
Based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures, the migration of additives used in the manufacture of the raw materials is not expected to exceed the applicable Specific Migration Limits (SMLs).

6. Handling and storing

All NOVOBOX and NOVOBIB products are manufactured, handled and stored under controlled conditions suitable for food contact materials.

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Finished products are stored in a warehouse connected to the production facility at:
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Storage conditions are controlled to preserve product quality and compliance throughout the declared shelf life.
The recommended storage conditions are:
• Indoor storage only
• Temperature: +15 °C to +30 °C
• Relative humidity: 40–70 %
• Protection from direct sunlight and UV radiation

Under these conditions, the declared shelf life of NOVOBOX and NOVOBIB products is 12 months from the date of manufacture.

Products shall be transported, stored and handled in a manner that prevents contamination, mechanical damage and deterioration that could affect their suitability for food contact applications.

7. Other Compliance Statements

Allergens

Based on our knowledge of the raw materials used and on supplier Declarations of Compliance, NOVOBOX and NOVOBIB products are not intentionally formulated with any of the allergenic substances listed in Regulation (EU) No 1169/2011 on the provision of food information to consumers.

Bisphenols & Phthalates

The raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to bisphenols and phthalates.

Based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures, Bisphenol A (BPA), Bisphenol S (BPS) and phthalates are not intentionally used in the manufacture of the raw materials used in NOVOBOX and NOVOBIB products.

Where applicable, compliance has been assessed taking into account:
• Commission Regulation (EU) 2024/3190 concerning bisphenols and certain bisphenol derivatives intended to come into contact with food;
• Regulation (EC) No 1935/2004;
• Commission Regulation (EU) No 10/2011;
• applicable U.S. FDA requirements; and
• relevant recommendations of the German Federal Institute for Risk Assessment (BfR).

PFAS Substances

The plastic raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to per- and polyfluoroalkyl substances (PFAS) within our ISO 22000 Food Safety Management System supplier approval and risk assessment procedures.

Based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures, PFAS substances - including, but not limited to, PFOS, PFOA, PFHxS, PFNA, long-chain perfluorocarboxylic acids (LC-PFCAs) (including their salts and related compounds), and PTFE - are not intentionally added to the products and are not intentionally used as processing aids in their manufacture.

To the best of our knowledge, PFAS substances are not present above applicable regulatory limits.

This assessment has been carried out taking into account:
• Regulation (EC) No 1907/2006 (REACH), including applicable Annex XVII restrictions;
• Regulation (EU) 2019/1021 on persistent organic pollutants (POP Regulation);
• Regulation (EC) No 1935/2004;
• Commission Regulation (EU) No 10/2011.

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We actively monitor ongoing regulatory developments concerning PFAS, including the proposed broad PFAS restriction under REACH, and will review and update this Declaration of Conformity as necessary.

Substances of Concern (SoC)
In accordance with Article 5(1) of Regulation (EU) 2025/40, Hutek Oy has established documented procedures for raw material approval, supplier qualification and compliance assessment designed to minimise the presence and concentration of substances of concern (SoC) throughout the life cycle of the packaging.

The assessment is based on supplier Declarations of Compliance, relevant technical documentation and applicable regulatory requirements. Continued compliance is maintained through the documented procedures described in the Compliance Assessment section of this Declaration.

Dual Use Substances
The raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to dual use substances as defined in Commission Regulation (EU) No 10/2011.

Where applicable, supplier Declarations of Compliance, compositional information and relevant technical documentation indicate that the migration of dual use substances is not expected to exceed the applicable limits established under European food legislation.

This assessment is based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures.

Heavy Metals
Based on supplier Declarations of Compliance, relevant technical documentation and our documented compliance assessment procedures, NOVOBOX and NOVOBIB products comply with Article 5(2) of Regulation (EU) 2025/40.

The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in homogeneous material does not exceed the maximum limit of 100 mg/kg (100 ppm).

Genetically Modified Organisms GMOs
Based on supplier Declarations of Compliance, relevant technical documentation and available product information, genetically modified organisms (GMOs) are not expected to be present in NOVOBOX and NOVOBIB products.

Mineral Oils MOSH/MOAH
The raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH).

According to supplier Declarations of Compliance and relevant technical documentation, MOSH and MOAH are not intentionally added as part of the formulation of the raw materials used in NOVOBOX and NOVOBIB products.

Other Plastics
Based on supplier Declarations of Compliance and relevant technical documentation, the raw materials used in NOVOBOX and NOVOBIB products are not intentionally formulated with:
- Polyvinyl chloride (PVC)
- Polyvinylidene chloride (PVDC)
- Polystyrene (PS)

Wooden Pallets
Based on supplier information and relevant technical documentation, the wooden pallets used for the storage and transport of NOVOBOX and NOVOBIB products are not intentionally treated with chlorophenols (CP) or bromophenols (BP).

Halal / Kosher / Vegan Suitability
Based on supplier Declarations of Compliance, relevant technical documentation and available supplier documentation, the raw materials used in NOVOBOX and NOVOBIB products are not intentionally derived from:
- pork or other meat-derived materials;
- animal fats;

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- animal-derived extracts;
- blood or plasma;
- other raw materials of animal origin; or
- ethyl alcohol.

Based on the information available, the equipment, production facilities, packaging materials and handling practices used in the manufacture, packaging and storage of NOVOBOX and NOVOBIB products are not intended to come into contact with the substances listed above.

This statement is based on currently available information and does not constitute Halal, Kosher or Vegan certification or replace any third-party certification requirements.

8. Post-processing

Certain NOVOBOX and NOVOBIB products intended for aseptic applications may be subjected to gamma irradiation within a dose range of 15-25 kGy.

Based on supplier Declarations of Compliance, relevant technical documentation and information provided by the irradiation service provider, the gamma irradiation process has been assessed with regard to food contact safety.

According to the available information, the irradiation process is not expected to adversely affect:
- the food safety of the packaged food;
- the integrity of the packaging materials; or
- the migration behaviour of the packaging under the assessed conditions.

Where required by Commission Regulation (EU) No 10/2011, verification of overall and specific migration compliance after irradiation remains the responsibility of the user of the final article under the intended conditions of use.

9. Recyclability

NOVOBOX and NOVOBIB products are manufactured from plastic materials intended for recycling through established plastic recycling systems, where suitable collection and recycling infrastructure exists.

Material	Material	Recycling label	Recycling instruction
Outer film	PE/EVOH/PE		Recycling as plastic waste
Outer film	MET/PET		Recycling as plastic waste
Outer / Inner film	LDPE/LLDPE		Recycling as plastic waste
Spouts	PE		Recycling as plastic waste
Closures	PE/PP		Recycling as plastic waste

Although the individual packaging components may carry different material identifications, all components are intended to be disposed of through appropriate plastic recycling systems in accordance with local waste management requirements.

10. PPWR Compliance

NOVOBOX and NOVOBIB packaging has been assessed with regard to the applicable requirements of Article 5 of Regulation (EU) 2025/40 on packaging and packaging waste.

Based on supplier Declarations of Compliance, relevant technical documentation, our documented compliance assessment procedures and to the best of our knowledge:

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• the packaging complies with the requirements of Article 5(1), supported by documented raw material approval, supplier qualification and compliance assessment procedures designed to minimise the presence and concentration of substances of concern throughout the packaging life cycle;
• the packaging complies with the requirements of Article 5(2), according to which the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in homogeneous material does not exceed 100 mg/kg (100 ppm);
• the chemical composition requirements applicable to the packaging material manufacturer under Article 5(5) have been taken into account through documented raw material approval, supplier Declarations of Compliance, specification management and change control procedures.

Compliance with the applicable requirements of Article 5 is supported by the documented procedures described in the Compliance Assessment section of this Declaration.

We actively monitor implementing acts, guidance and regulatory developments related to Regulation (EU) 2025/40 and will review and update this Declaration of Conformity as necessary.

11. Validity and General Statement

This Declaration of Conformity is based on the applicable legislation, relevant technical documentation and supplier documentation available on the date of issue.

This Declaration confirms that NOVOBOX and NOVOBIB food contact packaging materials comply with the applicable legal requirements relevant to Hutek Oy as the manufacturer of food contact packaging materials.

Where required by applicable legislation, including Commission Regulation (EU) No 10/2011, verification of the compliance of the final packaging under its intended conditions of use remains the responsibility of the user of the final article, as migration behaviour depends on the packaged food, contact time, temperature and other reasonably foreseeable conditions of use, which are not known to Hutek Oy as the packaging material manufacturer.

This Declaration remains valid for three (3) years from the date of issue unless:
• applicable legislation is amended or superseded;
• relevant supplier documentation or technical information changes;
• raw materials, manufacturing processes or product specifications are modified; or
• other information becomes available that may affect the conformity of the products.

Where necessary, this Declaration will be reviewed and updated to reflect such changes.

This Declaration of Conformity supersedes all previous versions.

12. Signature

Hutek Oy
Nastola July 8th 2026

Kalle Uusitalo, CEO
Hutek Oy