HUTEK OY
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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 products intended for use as food contact materials using virgin plastic materials such as PE/EVOH/PE, LDPE, LLDPE, metallised PET (MET.PET), PE and PP. The products are composed of multilayer films, glands and closures forming the inner and outer components of the packaging system.
As a manufacturer of food contact material packaging, Hutek Oy bases this declaration on information currently available, including declarations of compliance and other relevant documentation provided by its raw material suppliers.

This certificate applies to the following NOVOBOX and NOVIBIB products:
Products made from LDPE and LLDPE films
1001-1006, 1008-1009, 1011-1013, 1024
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, 1426-1428, 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

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.
- 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.

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- 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

4. Compliance with overall migration limit (OML)

Based on the information provided by our raw material suppliers, the films, glands, and closures used in NOVOBOX and NOVOBIB products are considered to comply with the overall migration requirements of Regulation (EU) **No 10/2011**. The overall migration is not expected to exceed OML < 10 mg/dm², assessed using a surface area to food mass ratio of 6 dm²/kg. Any simulants used, where applicable, have been selected in accordance with Annex III of Regulation (EU) **No 10/2011**.

In accordance with Regulation (EU) **No 10/2011**, it is the responsibility of the user of the final article, where necessary, to verify compliance with the overall migration and specific migration limits by testing the final product using appropriate food simulants, exposure times, and temperatures corresponding to the expected final conditions of use.

5. Specific Migration Limit (SML)

The monomers and additives used in the manufacture of the raw materials for which specific migration limits are established, and which are listed in Annex I or II of Regulation (EU) **No 10/2011** have been assessed, based on the information available, and are not expected to exceed the applicable migration limits. The assessment is based on declarations of compliance, compositional information provided by raw material suppliers and, where applicable, on migration modelling or other technical evaluations carried out in accordance with the principles set out in Annex V of Regulation (EU) **No 10/2011**.

CAS numbers are based on the declarations of compliance provided by our raw material suppliers.

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Specific migration limitations (SML)
Specific migration limits (SML) for certain substances are established under EU legislation. With respect to monomers and additives used in the raw materials, an assessment has been carried out based on the information currently available from raw material suppliers in order to evaluate potential compliance with the applicable SML requirements.

Monomers
EU Ref. No. 22660: SML 15 mg/kg (ppm)

Additives
For the purpose of this assessment, a surface area to volume ratio of 6 dm^2/l has been considered, in line with the general assumptions applied under Regulation (EU) No 10/2011. Based on the information available and the assessment performed, the migration of additives is not expected to exceed the applicable SML limits.

6. Handling and storing

All NOVOBOX and NOVOBIB products manufactured by Hutek Oy are stored in a storage facility connected to the factory at Tiilitie 1, 15560 Nastola Finland. The storage conditions applied to NOVOBOX and NOVOBIB products are suitable for food contact materials.

The shelf life of NOVOBOX and NOVOBIB products is 12 months, provided that the products are stored, handled, and used in accordance with the recommended conditions. Indoor storing at temperature between +15 to +30 °C and indoor air humidity between 40 - 70% is recommended. Products have to be protected from direct UV-light.

7. Other

Allergens
Based on our knowledge and on the information provided by our raw material suppliers, NOVOBOX and NOVOBIB products are not intentionally formulated with any of the allergenic substances listed in Regulation (EU) **No 1169/2011**.

Bisphenol-A, Bisphenol-S and Phthalates
Based on information currently available to us and on information provided by our raw material suppliers, the raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to bisphenols and phthalates. Where applicable, the materials are considered to be in line with relevant recommendations of the German Federal Institute for Risk Assessment (BfR), including Recommendation III for polyethylene, as well as with applicable requirements of U.S. FDA regulations (Title 21 CFR).

According to the information available, Bisphenol A (CAS No. 80-05-7), Bisphenol S (CAS No. 80-09-1) and phthalates are not intentionally used in the manufacture of the raw materials used in NOVOBOX and NOVOBIB products. These substances are not intentionally added as part of the formulation of NOVOBOX and NOVOBIB products.

Dual Use Substances
Based on information currently available to us and on information provided by our raw material suppliers, the raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to dual use substances as defined under Regulation (EU) **No 10/2011**. Where applicable, this assessment indicates that the migration of any such substances is not expected to exceed the applicable limits established under EU food legislation.

The assessment is based on declarations of compliance, compositional information and other relevant data provided by raw material suppliers. This statement is made on the basis of the information currently available and has not been verified by independent analytical testing.

Heavy metals
Based on information provided by our raw material suppliers, NOVOBOX and NOVOBIB products manufactured by Hutek Oy are not intentionally formulated with heavy metals such as lead, cadmium, mercury, or hexavalent chromium. This statement is based on supplier information and has not been verified by independent testing.

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Genetically Modified Organisms (GMOs)
Based on information currently available to us, including knowledge of the product composition and certificates provided by our suppliers, genetically modified organisms (GMOs) are not expected to be present in NOVOBOX and NOVOBIB products.

Mineral oils (MOSH, MOAH)
Based on information currently available to us and on information provided by our raw material suppliers, 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 this information, these substances are not intentionally added as part of the formulation of NOVOBOX and NOVOBIB products.

PFAS substances
Based on information currently available to us and on information provided by our raw material suppliers, the raw materials used in NOVOBOX and NOVOBIB products have been assessed, with regard to per- and polyfluoroalkyl substances (PFAS). According to this information, PFAS substances, including but not limited to PTFE, PFOS, PFOA, PFHxS, PFNA and LC-PFCAs (including their salts and precursors), are not intentionally added to the NOVOBOX and NOVOBIB products and are not intentionally used as processing aids in their manufacture.

This assessment has been made taking into account the requirements of Commission Regulation (EU) **2024/3190** on the use of bisphenols and certain other substances in materials and articles intended to come into contact with food, where applicable. This statement is based on supplier information and has not been verified by independent analytical testing.

Other plastics
Based on our knowledge of the product composition and on certificates provided by our raw material suppliers, the raw materials used in NOVOBOX and NOVOBIB products have been assessed with regard to the presence of other plastics. According to this information, polystyrene (PS), polyvinyl chloride (PVC) and polyvinylidene chloride (PVDC) are not intentionally used or added as part of the formulation of the raw materials.

Wooden pallets
Based on information provided by our pallet suppliers, 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 and Vegan
Based on information currently available to us and on information provided by our raw material suppliers, the NOVOBOX and NOVOBIB products manufactured by Hutek Oy have been assessed, with regard to the general principles of Halal, Kosher and Vegan suitability. According to this information, the raw materials used in the manufacture of NOVOBOX and NOVOBIB products are not intentionally derived from or formulated with:
i) pork or other meat-derived materials or by-products
ii) animal fats or animal-derived extracts
iii) animal blood or plasma
iv) raw materials of animal origin
v) ethyl alcohol

Based on the information currently 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. Alcohol-based substances are not intentionally used in the manufacturing, packaging, storage, maintenance or servicing of the production lines or facilities.

This statement is based on supplier information and internal process knowledge and has not been verified by third-party certification.

This statement does not constitute Halal, Kosher or Vegan certification and does not replace any third-party certification requirements.

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Post-processing
Aseptic NOVOBOX and NOVOBIB products may be subjected to gamma irradiation with a dose range of 15 to 25 kGy. Based on information available to us, including certificates and technical documentation provided by our raw material suppliers and the irradiation service provider, the applied gamma irradiation process has been assessed, with regard to food contact safety. According to this information, the irradiation is not expected to adversely affect the food safety of the packaged product, nor is it expected to adversely affect the properties of the packaging raw materials or their migration behaviour.

In accordance with Regulation (EU) **No 10/2011**, it is the responsibility of the user of the final article, where necessary, to verify compliance with overall migration and specific migration limits by testing the final product after the irradiation process, using appropriate food simulants, exposure times and temperatures corresponding to the expected final conditions of use.

Recyclability
The following raw materials are used in the production of NOVOBOX and NOVOBIB products:

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 raw materials of NOVOBOX and NOVOBIB products have two different recycling labels, they can all be recycled as plastic waste after use.

This Declaration of Conformity replace previous certificates and it is valid for 3 years from the date mentioned below.

Hutek Oy
Nastola January 23rd 2026

Kalle Uusitalo, CEO
Hutek Oy