

Landpack GmbH  
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D – 82239 Alling

Issued for:

Qiagen GmbH  
Qiagen Str. 1  
D – 40724 Hilden

## Clearance Certificate

***Landbox® Duo, Landbox® Bio***

This Clearance Certificate is issued for Qiagen GmbH on 10<sup>th</sup> July 2019.

We hereby declare, that *Landbox® Duo* and *Landbox® Bio* comply with the international regulations of GMP, GDP, and microbiological purity stated in the following.

Amendments:

- Compliance with international GMP Standards
- Compliance with international standards in cooling logistics – GDP
- Limit values microbiological tests



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# Compliance with international GMP Standards

## Production process

We hereby declare, that *Landbox® Duo* and *Landbox® Bio* comply with the regulations of (EU) Nr. 1935/2004 as well as with the European plastics-regulation (EU) Nr. 10/2011.

All Landpack® boxes are produced in compliance with international standards in the production of packaging with high hygienic demands (GMP).



EN 15593:2008 Packaging – Hygienic management in the production of packaging with high hygienic demands



(EG) Nr. 2023/2006 GMP - Regulation of Good Manufacturing Practice



(EG) Nr. 1935/2004 EU- Framework regulation for consumer goods

## Constituents

To produce *Landbox® Duo* and *Landbox® Bio* insulation panels, no ingredients other than dry straw of food quality are used. The straw is de-dusted, cleaned of foreign bodies and treated with saturated steam more than 100 °C. For the steam process potable water is used.

### **Landbox® Duo**

The used wrapping synthetic of *Landbox® Duo* complies with the regulation (EU) Nr. 10/2011. The following substances with restriction and/or specification are used in the synthetic:

Substance name	Restriction
Octadecyl	SML = 6 mg/kg
Antioxidant	SML = 0,6 mg/kg
Antistatic	Listed without restriction.

Tests on the synthetic of *Landbox® Duo* by an accredited testing institute (ISEGA GmbH) have confirmed, that none of the specific migration limits are exceeded, as far as the tests carried out are concerned and the conventional conversion factor surface/volume of 6 dm<sup>2</sup>/kg food was used.

The migration total of the synthetic has been tested under the following conditions: 3 % Acetic-acid (10 days at 40 °C), 10 % Ethanol (10 days at 40 °C) and 95 % Ethanol (10 days at 40 °C). The migration total lies below the total migration limit of 10 mg/dm<sup>2</sup> without application of one of the permitted reduction factors.

### Landbox® Bio

The used wrapping synthetic of Landbox® Bio complies with the regulation (EU) Nr. 10/2011. The following substances with restriction and/or specification are used in the synthetic:

Substance name	Restriction
PLA	PLA is listed as the monomer lactic acid in Annex 1, Table 1. No restriction.
Antistatic excipient The maximum theoretical amount of the substance is below the SML limit; therefore, a specific migration test is not required.	SML = 6 mg/kg
Processing aid	Listed without restriction.

The main application of the synthetic of the Landbox® Bio is in the storage and preparation of food. Therefore, an independent total migration test of the synthetic with simulants A & B for the duration of 1 hour at 100 °C has been conducted. The results lie below the threshold of 10 mg/dm<sup>2</sup>, based on 1 kg food with a migration of 60 mg/kg food. The tests have been carried out according to Smithers PIRA with a sample of 1 dm<sup>2</sup>. Additionally, a total migration test of the synthetic in 95 % ethanol has been conducted for 40 days at 40 °C and with iso-octane for 2 days at 20 °C. The thresholds were complied with.

No „Dual-use“ substances are used.

## Scope of application

This confirmation applies to the products supplied by Landpack and their use as specified. The conformity test was carried out in accordance with the above rules; the product then fulfils the legal requirements. In case of deviations from the intended use, the user is responsible for the conformity and suitability test.

The traceability of products under Regulation (EC) No 1935/2004 is ensured by the numbers affixed to the secondary packaging.

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## Compliance with international standards in cooling logistics - GDP

*Landbox®Bio* and *Landbox®Duo* have been pre-qualified according to (EU) Nr. 2001/83/EC. Compliance with international standards in cooling logistics is assured:



(EC) Nr. 2001/83 as well as its amendments

Community code relating to medicinal products for human use



55545-1

Test method for packing with insulating properties



7E 2010

Testing Standard for Thermal Transport Packaging Used in Parcel Delivery System Shipment (winter / summer profile)



D3101-14

Standard Test method for Thermal Insulation Performance of Distribution Packages



NF S99 – 700

Method for qualifying thermal performance of isothermal and refrigerated packaging for health products.

For proof please check the Performance Qualification Report.

This confirmation applies to the packaging method as recommended. The user is responsible for the actual packing method and further tests.

### Storage conditions

Based on flammability tests in accordance with DIN 4102-1, straw is considered as “normally flammable” and accepted as a building material of class B2. In a compressed form, it is concerned as building material of class B1. It can be stored like cardboard. For optimal storage conditions, the temperature in the warehouse should be between 15 and 20 °C with the relative humidity between 50 and 60 %. Under these conditions, a storage time of 6 months can be guaranteed.

## Limit values Microbiological tests

The company Landpack GmbH continuously carries out microbiological tests of its hemp and straw packaging as part of its QM system. By this measure a constant quality can be guaranteed, which corresponds to the legal requirements as well as the scientific state of the art. For microbiology, this essentially means that no pathogenic germs may be present on the insulated packaging and that the total germ count (CFU) should be 2 to 3 orders of magnitude below that of the contents 1). These requirements are met by the following applicable limit values.

### **Total bacterial count**

Threshold: 5 KbE/cm<sup>2</sup>

### **Mould fungi**

Threshold: 3 KbE/cm<sup>2</sup>

### **Yeasts**

Threshold: 5 KbE/cm<sup>2</sup>

### ***Enterobacteriaceae***

Threshold: 0 KbE/cm<sup>2</sup>

### ***Escherichia coli*** (detected by $\beta$ -Glucuronidase)

Threshold: 0 KbE/cm<sup>2</sup>

In addition, Landpack products are routinely tested by an external laboratory. With this procedure we validate our internal measurements.

From a microbiological point of view, foodstuffs whose bacterial count is 2 orders of magnitude (factor 100) higher than the limit values stated above may be in direct contact with the packaging.

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