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## Cleanroom packaging protects against contamination

Cleanroom production and packaging are a very important issue because the primary packaging has to preserve the product and process quality. Primary packaging for pharmaceutical and medtech products needs to meet the highest quality requirements. Hygiene and cleanliness are basic properties for plastic packaging materials. STRUBL Packaging has installed a highly professional cleanroom manufacturing process for cleanroom packaging materials based on ISO 14644.

Cleanroom production based on ISO14644 has become the standard for all markets that have to meet the highest requirements in hygiene and cleanliness, e.g. the pharmaceutical, medtech, lifesciences, and healthcare industries. These products are covered by continous quality management monitoring. This applies to active pharmaceutical ingredients (API) as well as plastic devices and components, implants, instruments, tubes, inhalers, valves, application tools, and numerous products used for laboratory applications and testkits.

Before leaving the cleanroom environment, these products have to be packaged to avoid any damage and contamination during subsequent handling and transportation operations. Therefore plastic packaging materials are the suitable solution. Plastic packaging materials such as bags, side-gusseted bags, zipbags, covers, films, and tubes are used in every step of the cleanroom process value chain as primary packaging materials.

## Cleanroom packaging – the best way to avoid contamination

To be sure, that the primary packaging meets the cleanroom requirements, these packaging materials have to be produced in a suitable cleanroom environment as well. Special risks have to be checked:

- raw material risks: migration between packaging material and product
- process risks: particle emission during the handling process





- > logistic risks: packaging specifications
- product risks: sealability, seal strength, non-leaking seals

## STRUBL cleanroom packaging

All products can be customised: the customer specifies dimensions and packaging requirements, such as labelling, as well as raw material conformities e.g. foodgrade/medicalgrade/pharmagrade. All products are suitable for gamma irradiation. If needed all products can be designed with antistatic surfaces.

cleanzip – zipbags in cleanroom quality STRUBL has developed a cleanroom zipbag. These reclosable bags are used for numerous applications, but until now these standard bags were not available in cleanroom quality. Cleanzipbags can be used for laboratory applications such as sampling, archiving, and intermediate packaging. Cleanzipbags are manufactured in a GMP-based production system and meet the high requirements of pharmaceutical applications required by the GMP quidelines.

## bag-in-bag - bagsystems

"Bag-in-bag systems" are systems that combine two or three bags. The bags are already placed within one another to simplify the packaging process for the customer. Thus the customer reduces their packaging efforts: with one single packaging process, both primary and secondary packaging are fulfilled. This reduces excessive handling and the risk of damaging the products.

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