TOMMY NIELSEN
Medical Packaging Solutions

Cleanroom

The cleanroom is used for processing sterile foil for use in the production of blister packaging. Quality is our top priority. We primarily operate within the medical industry, which demands the highest standards of cleanliness and material quality. Our materials comply with stringent industry requirements, regarding approvements and traceability.

Classified Cleanroom standard

The packaging materials are processed based on your products' specifications in a cleanroom tested "At-Rest" and as "Operational" for compliance with ISO 8 standard EN ISO 14644-1. This deals with the classification of air cleanliness in cleanrooms, clean zones and separate units. ISO class 8 sets the requirements for the number of particles in the room along with the pressure.

Cleanroom production follows the instructions specified in the guidelines "GMP for Medicinal Products". The requirement that must be met, is Class C / D:
Cleanrooms used for less critical phases in the production of aseptically filled sterile products as well as preparation/filling.

Tommy Nielsen's QMS system is based on the basic quality management principles of ISO 9001 and specified in the QMS Handbook, supported by SOPs for:

- Approval of incoming RAW materials from Suppliers
- Approval of Equipment
- Storage packing – Inventory Control
- Traceability from end user to raw material
- Sampling of samples
- Hygiene – Material handling
- Environment
- Internal Audit plan
- Clean room control
- Training of operators

Certified materials

We provide materials with certificates (CoC) ensuring compliance with the manufacturer's data sheet. This documentation guarantees that our material meets the specified standards, providing you with transparency and confidence in our products.

Tommy Nielsen ApS
Registration No. 32662641

Malervej 6 - DK - 6710 - Esbjerg V
Phone No. +45 75153200

info@tommynielsen.com
www.tommynielsen.com