eurofins | inpac

Our service, Your success

From raw product to market ready medical devices

Production of packaging material in clean rooms of ISO class 7

- Hard blisters (PETG, APET)
- Soft blisters (OPA/PE, medical paper, Tyvek®)
- Peel pouches (OPA/PE, PET/PE, medical paper, Tyvek®)
- Production of sealing lids (Tyvek®, medical paper) for hard blisters
- Digital colour printing on Tyvek®

Packaging design and development

- 3D-construction of standard, individual and transport blisters
- Thermoforming simulation software
- Making of prototypes

Cleaning of chemical, biological and particulate contamination

- Washing and disinfection machine, with and without detergent substances
- Rinsing bath with and without Isopropanol (IPA)
- Ultrasonic bath with and without IPA

Assembly of medical devices according to customer specifications

- ESD workplace for the assembly of electronic components

Logistic services

- Inpac vehicle fleet or service providers

Contract packaging

- With prefabricated blisters and pouches
- In-line production, packaging and labelling in hard/soft blisters and pouches

Sterilisation

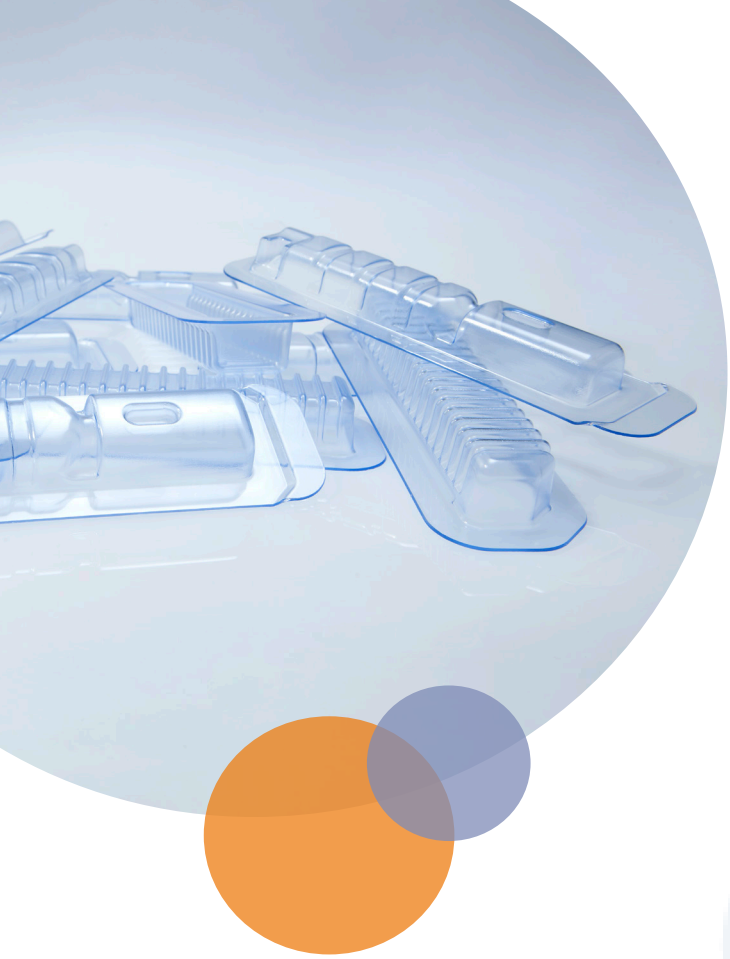
- Radiation at external partners
- Ethylene oxide at external partners or at in-house EO sterilisation plant

Labelling

- Label Design according to DIN EN ISO 15223-1 as well as UDI requirements
- Labelling of the products (including bar codes, data matrix codes etc.)

Procurement

- Procurement of product components (mechanical/electronic/chemical)
- Procurement of cardboard boxes and folding boxes
- Procurement of instructions for use and labels



Accompanying validations and documentations

The documents are generally issued in English. Further languages may be provided on demand.

Cleaning validations according to ISO 19227

- Investigation of bioburden ISO 11737-1, USP [61]
- Investigation of particle reduction USP [788]
- Investigation of cytotoxic substances, ISO 10993-5
- Investigation of endotoxins, USP [85]
- Investigation of organic and inorganic residues ISO 10993-12, -15, -18
- Biocompatibility ISO 10993-1

Sterilisation validations

- According to DIN EN ISO 11137-1,-2,-3 (gamma)
- According to DIN EN ISO 11135 (ethylene oxide)

Packaging validation

- DIN EN ISO 11607-1,-2, DIN EN 868-5, ASTM F1140, F88/F88M, ASTM F1929, ASTM F3039
- Accelerated aging ASTM F1980
- Real-time aging according to an internal standard

Transport Simulation

- ASTM D4169 DC 13, ISTA 2A, ISTA 3A, with pre-conditioning according to ASTM D4332

Packaging tests

- Visual inspection, ASTM F1886
- Seal strength test, DIN EN 868-5 and/or ASTM F88/F88M
- Dye penetration test, ASTM F1929, ASTM F3039
- Burst test, ASTM F1140
- Investigation of the microbiological barrier property DIN EN 58953-6
- Bubble test ASTM F2096

Safe. Sterile. Packaging.

Services

Production of packaging material • Packaging design

Cleaning • Assembly • Procurement management

Packaging • Sterilisation • Validation • Labelling

Contact us

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