# <u>Dordan</u>



### Dordan is an ISO 9001:2015 Certified designer and thermoformer of medical packaging with ISO Class 8 Cleanroom manufacturing.

Dordan is a 60-year old, family-owned and operated custom thermoformer with in-house packaging design and engineering, tooling, and cleanroom manufacturing.

## In-House Medical Packaging Design & Manufacturing:

- NX Packaging Design & Tooling
- **▶** ISO Class 8 Cleanroom Manufacturing
- **▶** ISO 9001 : 2015 Certified QMS

#### **Medical Packaging Types**

Medical device trays
Clamshells/Containers
Surgical & procedural kits
Medical components
Pharmaceutical blisters
Dunnage Trays

### **Customers Served**

Medical device designers

Medical OEMs

Contract manufacturers

Medical assembly & logistics

Packaging design & tooling: Dordan uses Solid Model NX for the design of medical packaging and thermoform tooling. Dordan develops packaging with a collaborate and multi-departmental, risk-based approach. The same teams of engineers that create the thermoform design also generate the NX CAM/CNC-produced aluminum tooling. This allows for more intelligent quality control, as there are no translation errors between package design and tooling. This integrated approach results in the production of consistently high quality medical packaging in short turnaround at competitive pricing.

Cleanroom Manufacturing: Dordan's ISO Class 8 Cleanroom, constructed on-site in 2019, is a 3,200 square-foot hard wall and fully enclosed space dedicated to the production of sterile medical packaging. 2019 Kiefel Speedformers offer best-in-class forming, cutting, and stripping stations. Dordan's goal is to provide safe and effective medical packaging through the minimization and management of particulate and bio-burden, per the requirements of its cleanroom certification.

**Quality Control:** Dordan offers first article inspection validation procedures (FAI) and full process validation procedures (IQ/OQ/PK). All QC procedures are based on Dordan's ISO 9001:2015 risk-based approach to quality management systems. Rapid digital imaging allows for the objective analysis of production parts in order to ensure target CPK per customer-specified critical dimensions.