



MIDWEEK COFFEE BREAK

From Prototype to Reliable Series Production: Lessons from an ISO 13485 MedTech Case

15 July 2026



Personal introduction



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Sales Director



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Introduction of The BKB Precision Group

BKB Precision Group

Established in **1982**
140 employees
24,1 mio EUR revenue (2025)
 > **60** turning and milling machines
 Medical, Analytical, Semicon, Defence, Food
 -**30%** by 2030 **CO₂** reduction goal (2023 = 0)
22% CO₂ reduction **achieved** (2025)



BKB Precision

Ultra high precision & Complexity
 High mix, low volume
 Engineering department
 Vertical integration

Son en Breugel

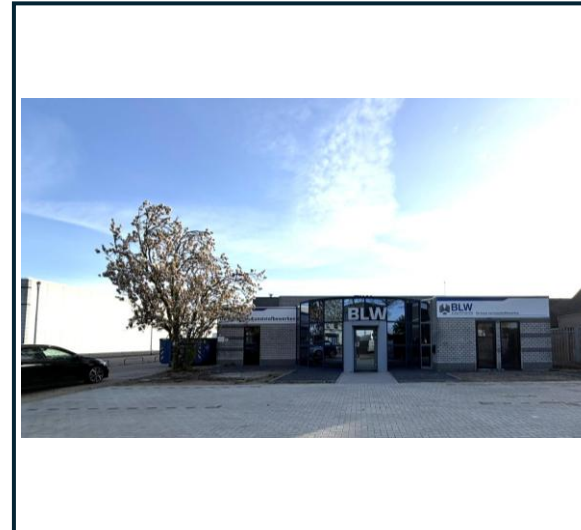
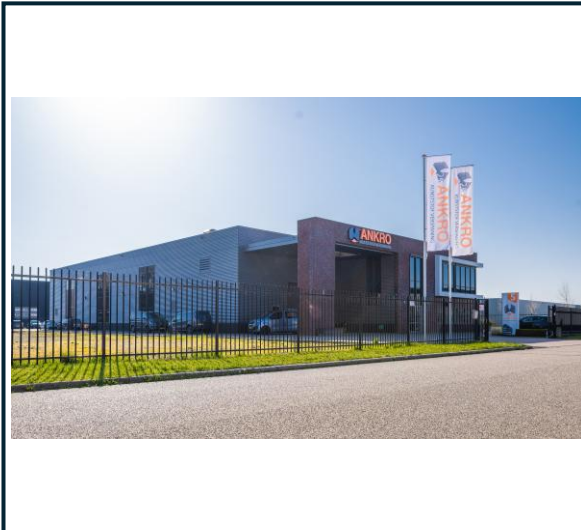


ANKRO Kunststofverspaning

High quantities up to x0.000 pieces
 Fast turnaround
 Pragmatic approach
 Specialist in turning



Werkendam



BLW Kunststoffen

High precision
 Mid-range series volumes
 Fit-for-purpose
 Milling, cleaning and assembly

Nuenen

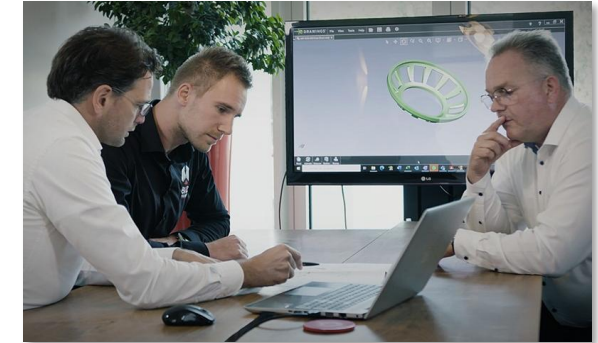


PEP: Product Efficiency Partner



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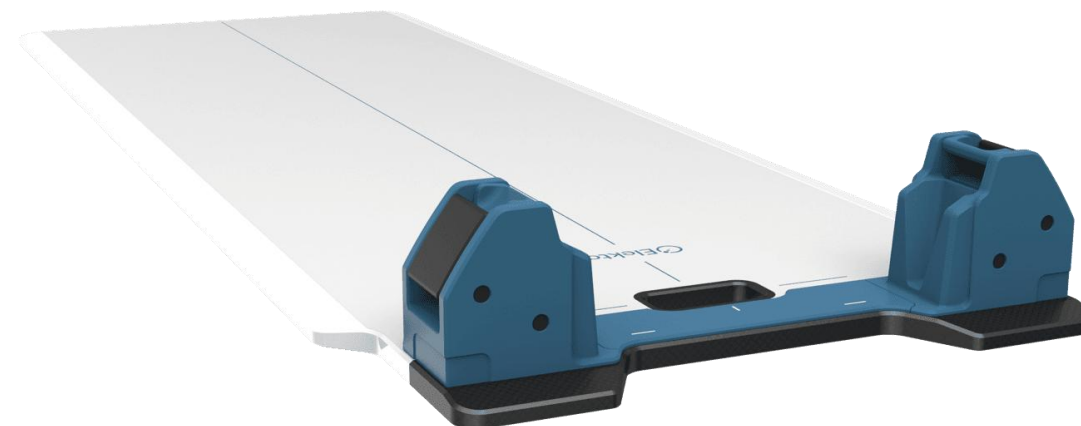
- A customer in the medical industry contacted BKB for an offer to develop parts for a new type of treatment method together.
- Concept not 100% proven yet.
- BKB Group selected as 1 of 3 potential suppliers
- Visit of the customer to BKB Group
- Each potential supplier was to supply a prototype
- Selection was done based on both hard and soft skills:
 - 1st delivery of prototype
 - Capabilities within the company
 - Cooperation level of the company
- BKB Group was selected as reliable partner for the future!



Starting point: the current product



The result of the project



Our challenge:

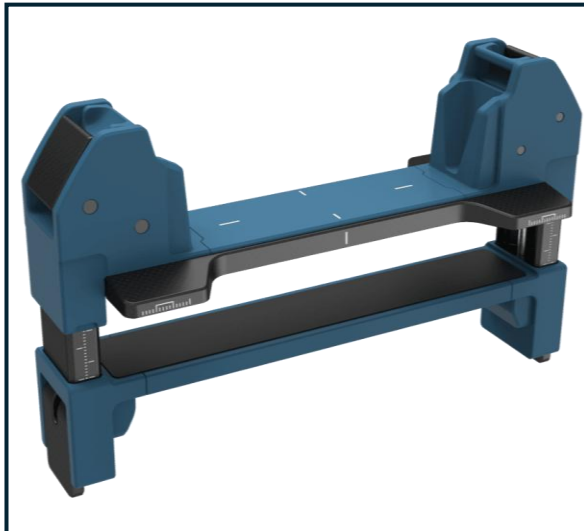
Time-to-Market



Perfect appearance demanded



Production Techniques



Documentation
ISO13485



1: Time to Market

Phases are set in time together with customer:

- Prototype 1 (P1)
- Prototype 2 (P2)
- Verification Production (VP)
- Preseries Production (PP)

Original timeline:

- Start: April 2024
- End: Mid 2026

Realisation:

- End 2025 delivery PP



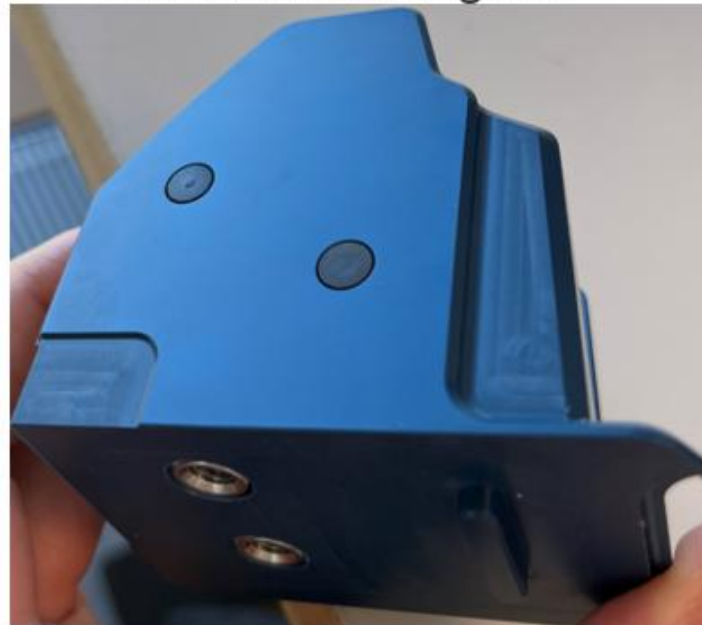
2: Perfect appearance demanded

BKB is used to deliver perfect parts with measurement!

Switch to product appearance → Mindset!

Appearance Approval Guide made for all parts

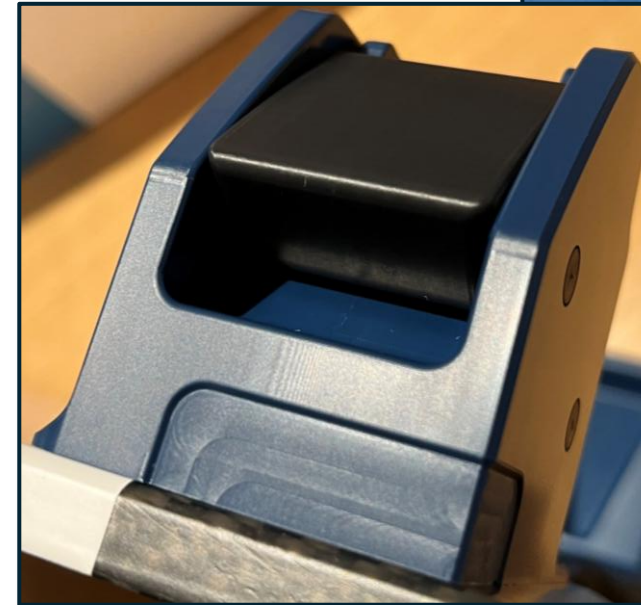
Side that looks good



Side with milling marks

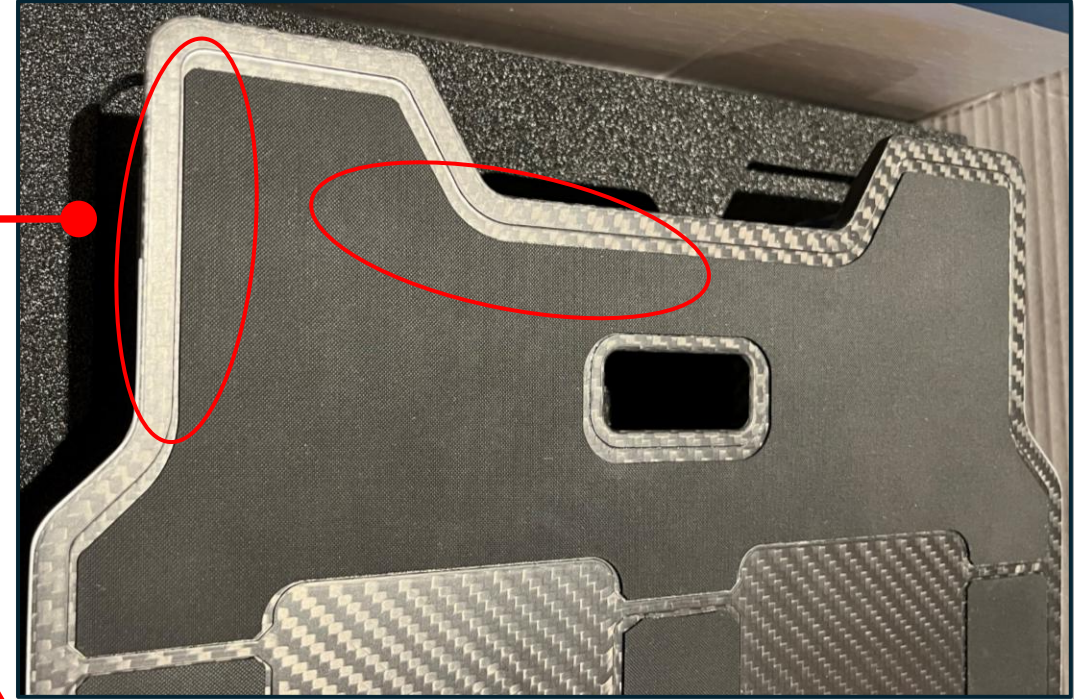


2: Perfect appearance demanded

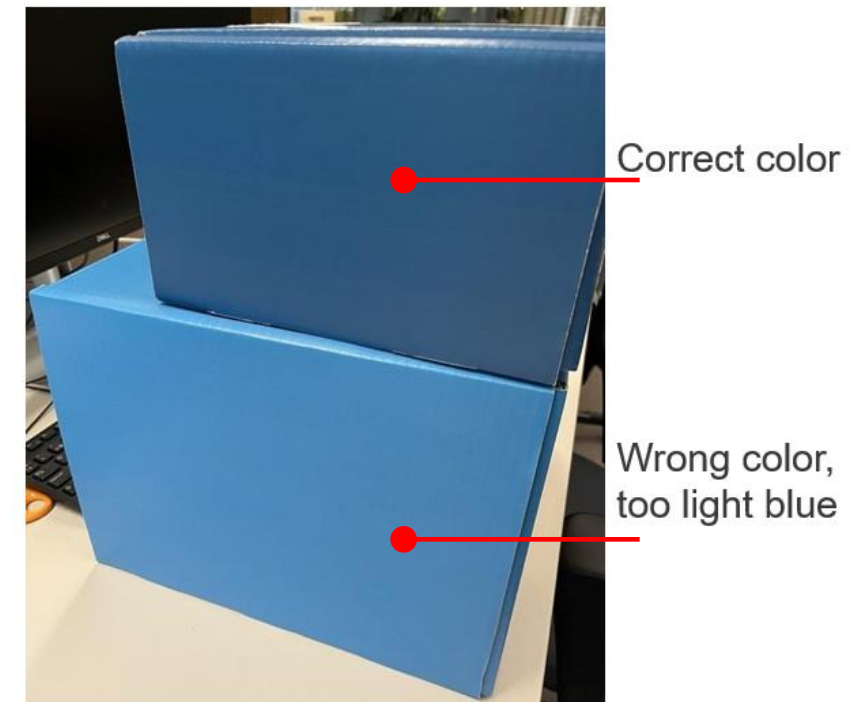
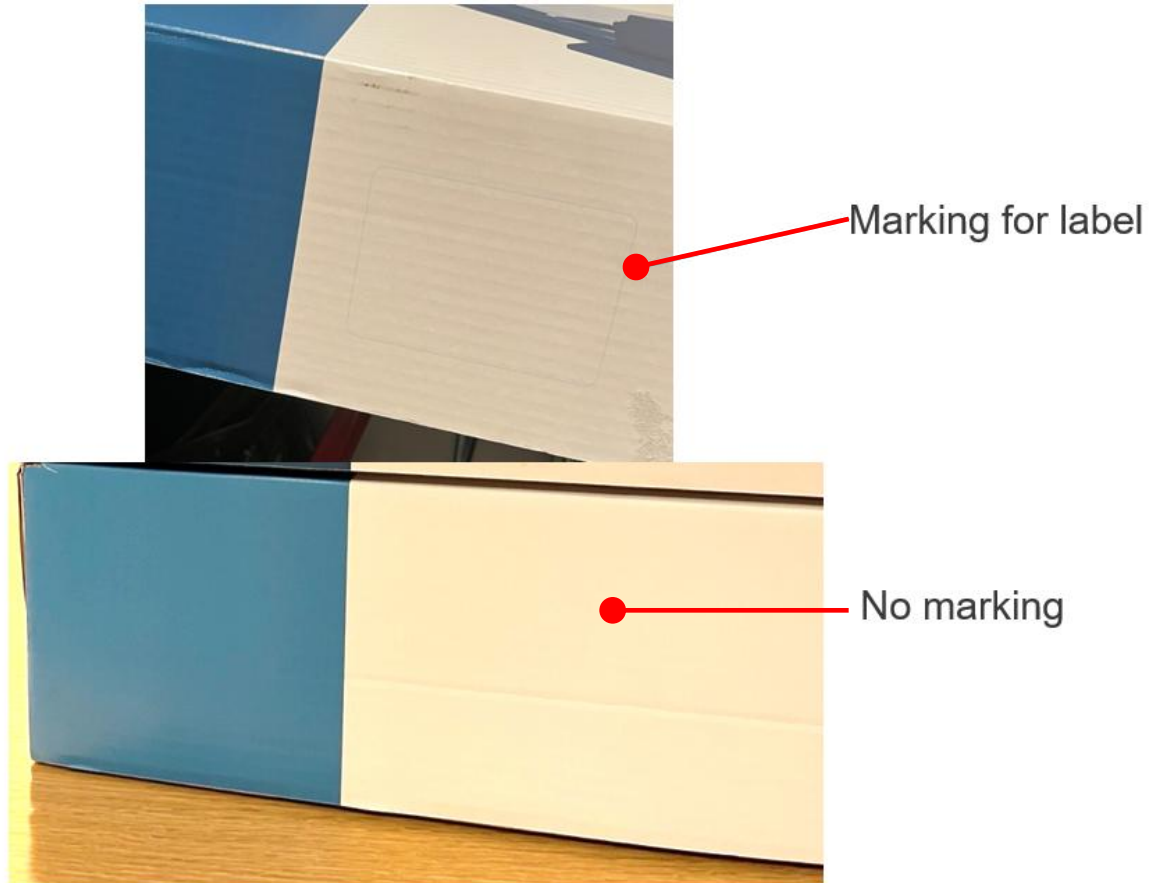


2: Perfect appearance demanded

Uneven placement of rubber

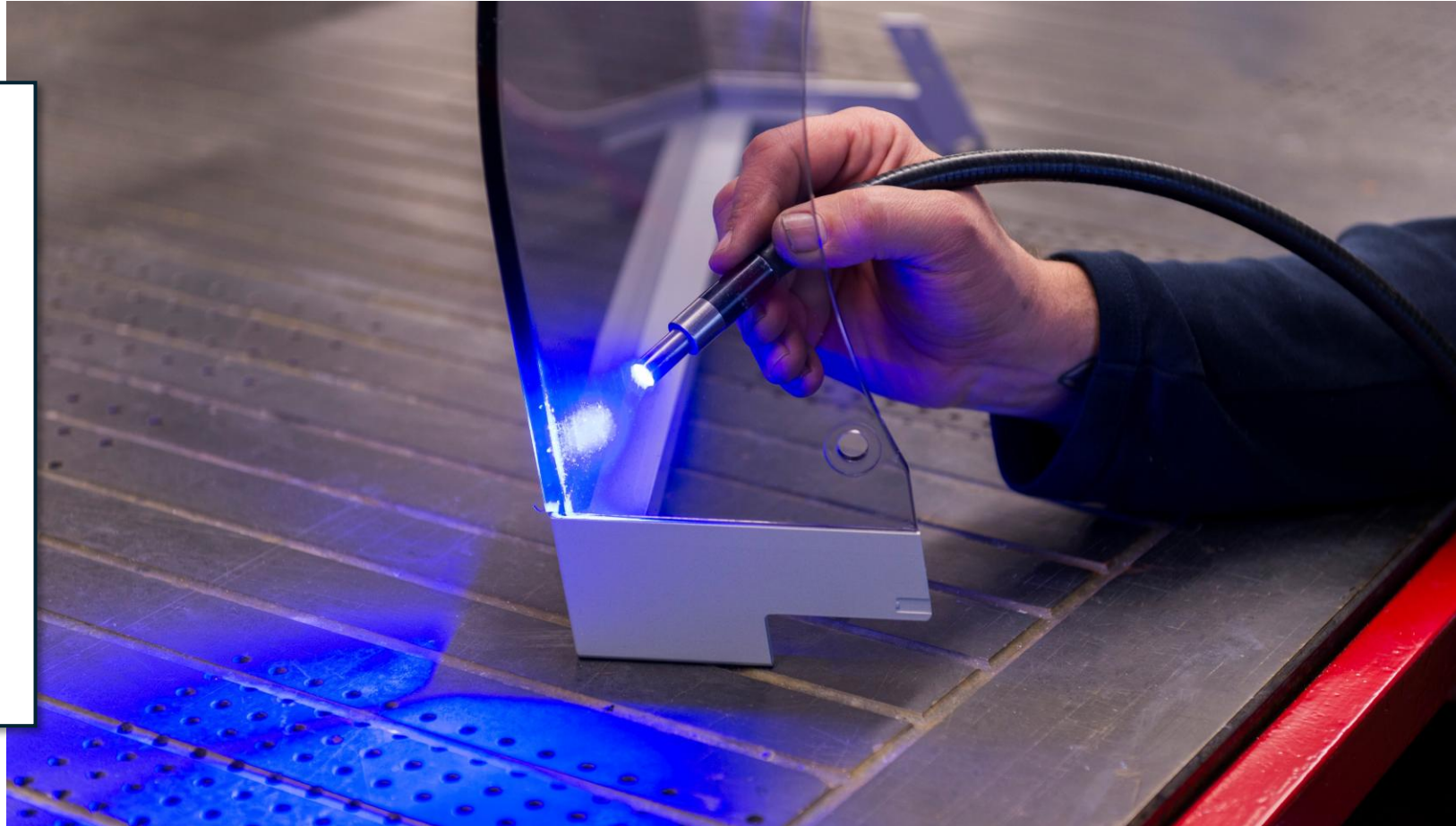


2: Perfect appearance demanded

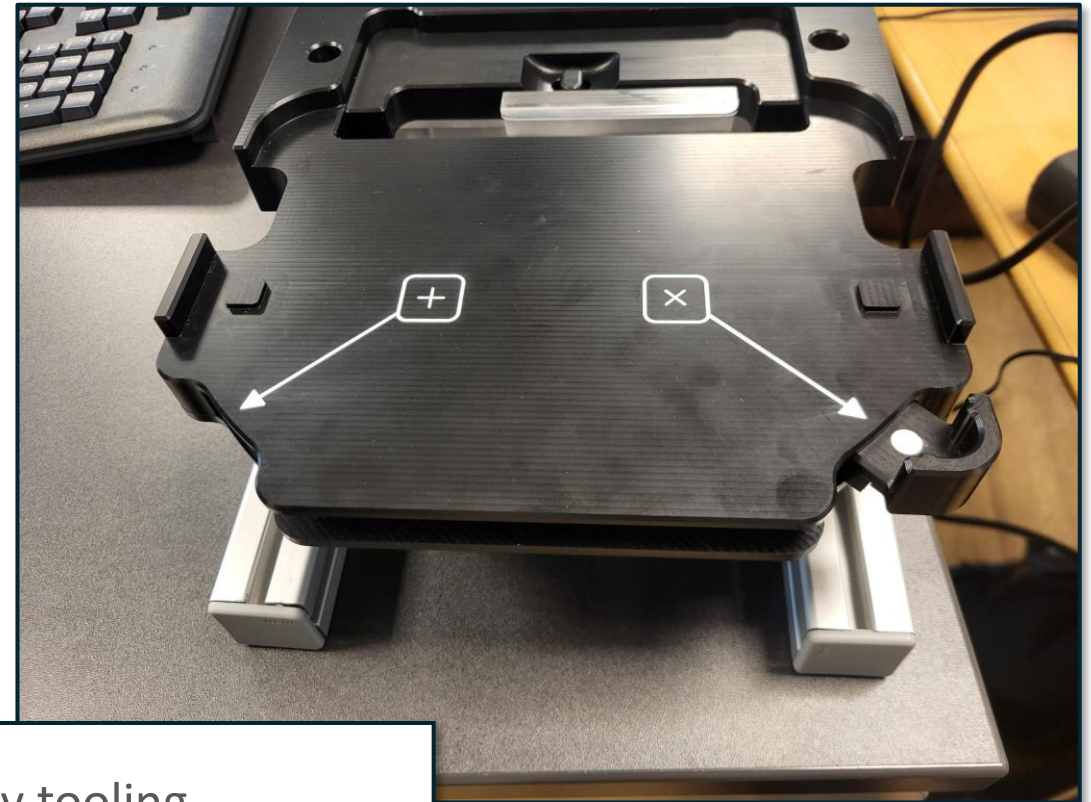


3: Production techniques

- Adhesive bonding tests
- Production techniques:
 - Gluing
 - Tooling
 - Programming CNC Machines
 - Used materials
 - Testing

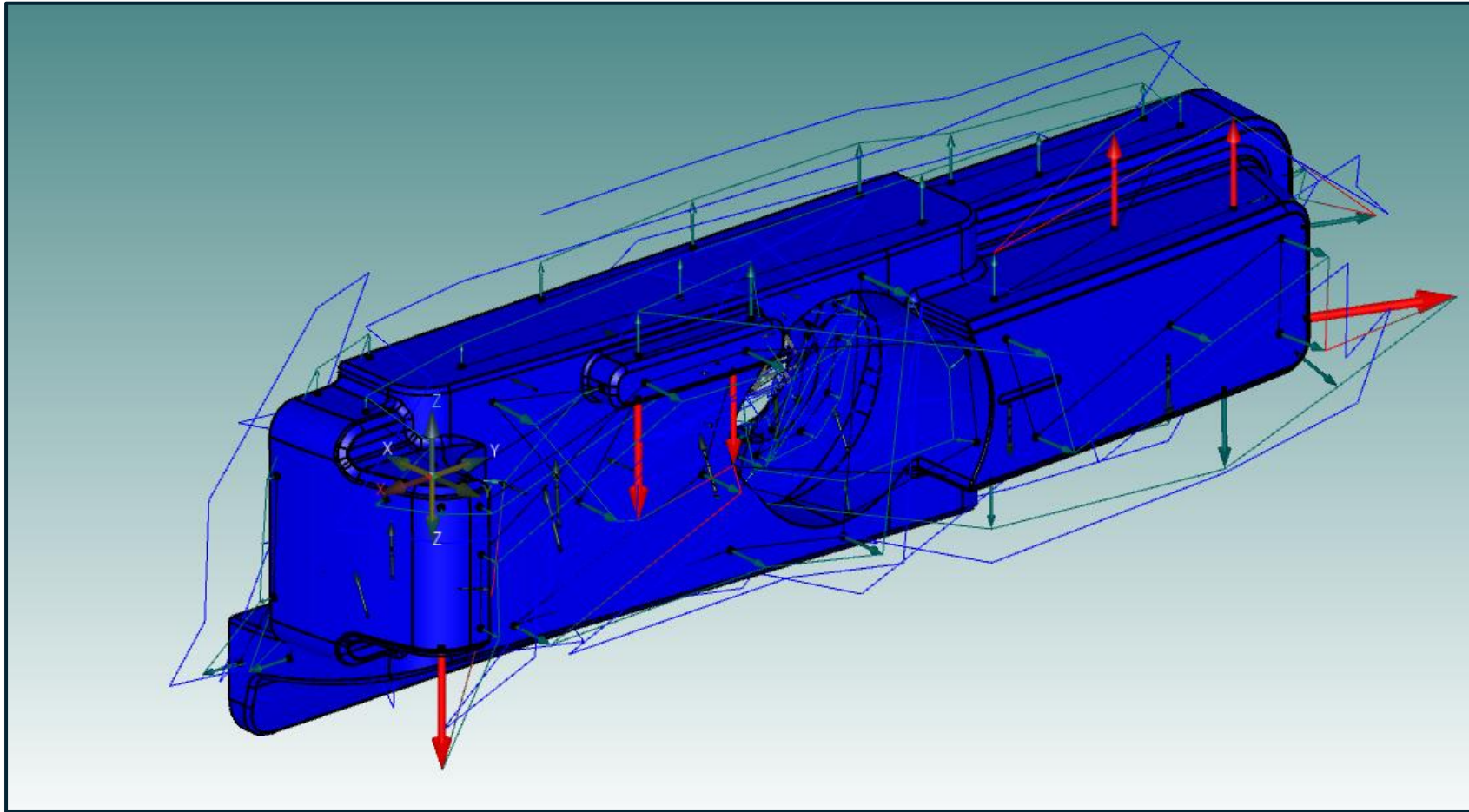


3: Production techniques (Tooling)



Special assembly tooling

3: Production techniques (Programming)

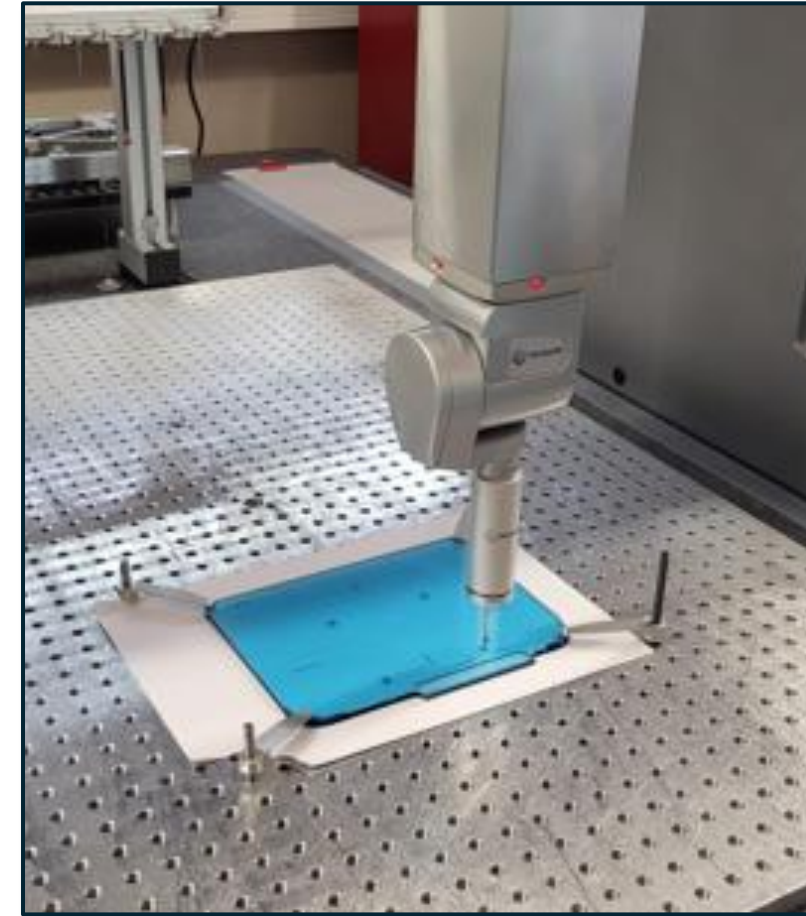


3: Production techniques (Used Materials)

- Colour
 - Plastics do not commit RAL colouring
- Glue strength
 - Testing
 - Pre-treatment
- Function:
 - Squeeck → PA6 becomes PA6 MOS2 (with oil)
 - Combination with laser engraving
 - Imaging Fiducial material → Gold → Tungsten
- Labels



3: Production techniques (Testing)



4: Documentation ISO13485

- PPAP
- PFMEA
- Control Plan
- Flowcharts
- Approval Appearance Guide
- Workinstructions:
 - Handling material
 - Gluing
 - Assembly
- Validation:
 - Operators
 - Processes
 - Packaging
- DHR (Device History Records)



4: Documentation ISO13485 (A.A.G.)

Example	
Not acceptable	Acceptable
	
Uneven surface structure on main surface	Smooth main Surface

Example	
Not acceptable	Acceptable
	
Uneven surface structure on main surface	Smooth main Surface

Example	
Not acceptable	Acceptable
	
Scratches on visible surfaces	No scratches

Lessons learned



- Mindset!
 - From measurement quality to visible quality
- Planning of project deliveries
 - Be clear what is possible and what not!
- Improve project way of working
 - Changing drawings after final release causes delays.
 - Improve 'Resolve open issues' for planning and quality of the project
- More often physical contact
 - When customer is abroad, then regular physical contact is necessary for good understanding.
- Cost sharing
 - Plan regular meetings only about the costs and progress of the project.
- Project knowledge and responsibilities more spread in the organisation
 - PPAP Deliverables, MS Teams usage for exchanging documents, project responsibilities

Other product examples - Assembly

A calibration unit for MRI scanner alignment. Plastic components were CNC-machined, assembled with buy parts, and fully measured as a complete assembly.



Medical device comprising BKB-machined plastic components and metal buy parts. Assembled and packaged by BKB in accordance with precise instructions. Ready for use.

Questions?





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