

12 questions to ask an ISO 13485 injection moulding partner

A buyer's checklist for medical-device component sourcing in Europe. The certificate is the entry ticket, not the decision - these twelve questions, and the warning sign under each, separate certificate-holders from partners.

1

Read the certificate itself, not the claim

Ask — For the certificate PDF. Verify the certifier, accreditation (e.g. DANAK, UKAS, DAkkS), scope wording and validity dates.

Watch for — Certification documentation that is unavailable, out of date or inconsistent with the services being offered.

2

QMS maturity - how many audit cycles has it undergone?

Ask — How long has the QMS been certified? How many recertification cycles has it completed? When was the last customer audit, and may we conduct one as part of supplier qualification?

Watch for — Certification obtained recently, with little audit history behind it.

3

Role clarity under MDR

Ask — Describe your role under MDR. Which ISO 13485 requirements are excluded from your certification scope, and why?

Watch for — Claims that components are "MDR certified" or "MDR compliant" - components are not CE-marked under MDR; medical devices are.

4

One team from prototype to volume

Ask — Who carries the project from prototype through validation and into volume production? Will the same site and engineering team remain responsible throughout?

Watch for — "We have partners for production" - that is a handover with a friendly name.

5

Prototypes in production materials

Ask — Can you provide functional prototypes in the intended production material, including multi-component (2K/3K) parts? What lead times, tooling requirements and costs are involved?

Watch for — Prototyping offered only in 3D-print resins or substitute materials, with production material available only after full tooling investment.

6

Validation as routine, not exception

Ask — Describe your standard validation approach for a new medical-device component. Can validation be performed at component level to our requirements?

Watch for — Validation described as "available on request" with no standard procedure behind it.

7

Cleanroom claims with the standard attached

Ask — Which cleanroom standard and classification apply? Which operations - moulding, assembly, inspection, packaging - are performed within the classified environment? How is it monitored and verified?

Watch for — An "ISO-certified cleanroom" without a stated standard, classification or clear description of what runs inside it.

8

Traceability from resin lot to shipped component

Ask — If we identify a shipped batch, how far back can you trace it - and how fast? How are raw-material suppliers evaluated and required to notify you of changes?

Watch for — Claims of full traceability that cannot be demonstrated through a practical retrieval example.

9

Material mastery for your component class

Ask — Which material classes do you master at compound level? Can you support material selection against performance, regulatory and manufacturing requirements - and document provenance?

Watch for — "We mould all materials" with no depth in yours.

10

Will the supplier still exist for your device's regulated life?

Ask — Who owns the company, and for how long has the current ownership structure been in place? What is the longest-running customer relationship currently supported in production?

Watch for — Ownership questions answered vaguely, or a supplier history defined by acquisitions and strategy resets.

11

Volume economics in Europe - automation, not promises

Ask — What share of your production runs automated? Can we see the production floor - physically or on video? How do you quote at 10x, and at 100x, current volume?

Watch for — European location sold as a value in itself, with no automation story behind the unit price.

12

Sustainability data you can put in your report

Ask — Can you provide component-level CO2 data for our parts - and from what system? Do you hold a Science Based Targets initiative commitment, and what is the registration?

Watch for — A sustainability page full of intentions, with no numbers available at component level.

About Carmo

Carmo A/S takes medical and demanding technical plastic components from first prototype to regulated volume — one engineering team, no handover. ISO 13485-certified, independently owned since 1941.

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