

Regulation Before Scale.

Six European companies. One structural pattern.
By the time it's called compliance, most decisions are already made.

Nuclivision · Wearable Robotics · Flok Health · Liliium · Volocopter · Babylon
By the time it's called compliance, most decisions are already made.





**Regulatory readiness seems optional
until scale makes it structural.**

**"Regulation is not a constraint on growth;
it is a design choice made before growth begins."**



THE SUCCESS CASES

Regulatory clarity in place before commitment.

01	02	03
<p>Nuclivision BELGIUM . MEDTECH SEED (2025)</p>	<p>Wearable Robotics ITALY . REHABILITATION ROBOTICS . SERIES A (2025)</p>	<p>Flok Health UK . DIGITAL HEALTH . PRE-SEED (2022) → CE MARK (2025)</p>
<p>€5M RAISED AFTER CE MARK CLASS IIa WAS ALREADY SECURED</p>	<p>50+ UNITS IN 20 COUNTRIES BEFORE CLOSING €5M SERIES A</p>	<p>1ST AI IN EUROPE APPROVED FOR FULLY AUTONOMOUS E2E CARE</p>
<p>Nuclivision obtained CE marking for NUCLARITY — AI software that enables PET scans with around 50% less dose and/or scan time without compromising diagnostic image quality — before closing its €5M seed round in 2025. Regulatory proof before capital.</p>	<p>Wearable Robotics, an Italian rehabilitation robotics company, raised a €5M Series A for its ALEX RS upper-limb exoskeleton, already deployed in over 50 installations across more than 20 countries at the time of the round. Clinical evidence preceded capital.</p>	<p>Flok Health operates a CQC-regulated, Class IIa AI musculoskeletal platform used across multiple NHS regions, delivering autonomous, AI-guided care within a regulated framework. The regulatory decision was made at pre-seed; the scale followed.</p>
<p>PROOF TYPE: CERTIFICATION BEFORE CAPITAL</p>	<p>PROOF TYPE: DEPLOYMENT BEFORE ROUND</p>	<p>PROOF TYPE: REGULATORY ARCHITECTURE BEFORE SCALE</p>

Regulatory clarity was in place before the next commitment was made.



THE LEARNING CASES

What regulatory gaps scale exposed first.

04	05	06
<p>Lilium</p>	<p>Volocopter</p>	<p>Babylon Health</p>
<p>GERMANY . eVTOL . SEED (2015) → LISTED → INSOLVENCY (2025)</p>	<p>GERMANY . eVTOL . SEED (2011) → SERIES D → INSOLVENCY (2024)</p>	<p>UK . DIGITAL HEALTH . SEED (2013) → LISTED → INSOLVENCY (2023)</p>
<p>\$1.5B</p>	<p>€750M+</p>	<p>\$4.2B</p>
<p>DEPLOYED BEFORE EASA CERTIFICATION WAS COMPLETE</p>	<p>RAISED BEFORE EASA CERTIFICATION WAS COMPLETE</p>	<p>VALUATION BEFORE PRODUCT WAS CLASSIFIED AS MEDICAL DEVICE</p>
<p>Lilium deployed well over a billion dollars while EASA type certification slipped into the mid-2020s and remained incomplete. First insolvency in October 2024, then a failed rescue and a second filing in February 2025.</p>	<p>Volocopter raised several hundred million euros and was only part-way through the third of four EASA audit stages when funds ran out, leading to insolvency in late December 2024. Certification ran in parallel to growth, not as a prerequisite.</p>	<p>Babylon marketed its AI symptom checker as a diagnostic-style tool, but it was never regulated by the MHRA as a diagnostic device; amid mounting safety concerns, NHS contract issues and losses, the company collapsed into insolvency in 2023.</p>
<p>GAP: CERTIFICATION DECIDED AT SEED. EXPOSED AT SCALE.</p>	<p>GAP: CERTIFICATION TREATED AS TIMELINE. NOT DESIGN.</p>	<p>GAP: PRODUCT NEVER CLASSIFIED. GAP EMBEDDED AT SEED.</p>

When pressure arrived, the regulatory gap was already locked in.



WHAT ACTUALLY SEPARATES THEM

Regulatory readiness looks optional until scale makes it structural.

"Regulation is not a constraint on growth. It is a design decision made before growth begins."

IN THE SUCCESS CASES

Proof existed before capital hardened.

Nuclivision CE-marked before raising. Wearable Robotics deployed in 20 countries before closing its round. Flok Health built regulatory architecture at pre-seed. Each had the regulatory fact before the capital commitment.

IN THE LEARNING CASES

The gap existed before scale exposed it.

Lilium and Volocopter treated EASA certification as a timeline, not a design input — that choice was made at seed. Babylon marketed an unregulated product as diagnostic from day one. In each case, the gap was structural by Series A. Scale made it terminal.

THE STRUCTURAL INSIGHT

The question is not whether regulation will matter. The question is whether it is a design decision at seed — or a compliance problem at scale, when the capital structure has already locked it in.



FOR FOUNDERS

What regulatory assumption in your product still has not been tested early enough?

Design for it now. By Series A it shapes your cost base.
After that it is harder to reverse.

FOR INVESTORS

What is still described as future compliance, but should already exist as design proof?

Ask for the regulatory design at seed.
By Series A it should be proven, not planned.

Maan

We work with founders and investors on clarity before investing.
Each edition distils one scaling lesson from six real European company trajectories.

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