

ZNEXT invests €150,000 in Ardeevo, the startup using AI to unlock medical technologies awaiting CE marking

AI agents and regulatory experts work together to help startups and SMEs prepare the documents needed to sell medical devices and diagnostics in Europe, at a fixed price and on defined timelines

For the industrial platform founded by Zanichelli, it is the fifth company in its portfolio in less than a year

English translation of the Italian press release issued on 5 October 2026. The Italian version prevails.



Giovanni Stracquadaneo (left), co-founder and CEO, and Alessandro Santopaolo, co-founder and CTO of Ardeevo

Milan, 5 October 2026 — No medical or diagnostic device can be sold in Europe without CE marking. From pulse oximeters to diagnostic software, more than 106,000 product families must go through this process today, yet only 71 bodies in total are authorised to carry it out, with ever-shrinking staff. On one side, people who need more effective diagnosis and care have to wait longer; on the other, the companies that develop these technologies, 90% of them startups and SMEs, rarely have an in-house regulatory team able to handle the required documentation. **Ardeevo** was created to provide them with exactly this expertise.

Behind the Rome-based startup, co-founded with **ZNEXT**, is the meeting of legal and technological expertise of its two founders: **Giovanni Stracquadaneo**, a legal expert, lecturer in healthcare innovation and serial entrepreneur, and **Alessandro Santopaolo**, an expert in artificial intelligence applied to healthcare and robotics.

Less hourly consulting, more results at a fixed price

Ardeevo supports companies along the entire regulatory pathway of their devices, from product qualification and classification to delivery of the technical file. The entry point is **Clark**, the platform's regulatory assistant, which gathers information through a guided interview and indicates the next steps along the way.

Based on this information, a system of artificial intelligence agents consults a knowledge base of hundreds of regulatory documents, drafts the sections of the technical file, links each statement to the regulatory reference it derives from and checks the overall consistency of the dossier. No document is released without mandatory review by an expert.

It is precisely this combination that sets Ardeevo apart. According to a mapping of **70 industry players carried out by the startup, none currently combines**, in a single AI-native platform, **consistency checks** across the entire technical file, **selection of the notified body best suited** to each device and **systematic review by regulatory experts**.

The business model turns consulting on its head: a fixed price per risk class, defined delivery times and payments tied to progress milestones. As required by European legislation, the technical documentation remains the

responsibility of the manufacturer, and conformity assessment is carried out by the notified body. Ardeevo works upstream, in the phase where most delays and costs are concentrated today.

“Today, regulatory affairs are seen as an obstacle to be tackled at the end of a project, when the product has already been built and every correction costs time and money. We want to bring them to the start of the journey and turn them into an advantage, because those who know the rules from day one design better and reach the market sooner,” says Giovanni Stracquadaneo, co-founder and CEO of Ardeevo. “In other words, Ardeevo gives startups and SMEs the same regulatory expertise that large companies can count on, without the burden of an in-house team.”

The fifth venture in ZNEXT's portfolio

As with every startup in its venture building programme, **ZNEXT joins Ardeevo as a co-founder**, with a **pre-seed investment of €150,000**, ongoing **operational support** and **access to the expertise and network of the Zanichelli Group**. Ardeevo thus becomes the fifth company of the industrial platform launched on Zanichelli's initiative, after Ekory, Pausetiv and Zetamed, launched within the

venture building programme, and Factanza Media, in which ZNEXT acquired a majority stake last April.

The choice looks to **a large market**. The European medical and diagnostic technology market **is worth around €170 billion**, 26.4% of the global total, second only to the United States. According to Ardeevo's market estimates, spending on compliance with the MDR and IVDR regulations will reach around €22 billion by 2033.

“Bringing artificial intelligence into a regulated sector such as medical technology means changing the way thousands of companies work, starting with SMEs and startups. They are the ones most affected today by the imbalance of a sector in which demand for certification is rising while the capacity to assess it is shrinking,” says Elena Lavezzi, CEO of ZNEXT. “Ardeevo is exactly the kind of company we want to build. Giovanni and Alessandro have complementary skills, know the problem from the inside and have identified a market that until now has been only partly served. Our role is to give this insight the industrial strength to become a company.”

ZNEXT

ZNEXT is an industrial platform that builds and accelerates technology companies in education, work and wellbeing. Founded in 2025 on the initiative of Zanichelli Holding, it combines Venture Building and a structured M&A plan as tools of a single industrial vision: investing in new ventures and strengthening high-potential companies, supporting their growth with a long-term perspective. ZNEXT operates as an autonomous and independent entity, sharing the values of a group that has been building knowledge for more than 160 years. For more information: www.znext.io

Ardeevo

Ardeevo is the RegTech startup that supports healthcare companies in drafting the technical documentation required for the CE marking of medical devices and in vitro diagnostics, under the European MDR and IVDR regulations. The platform combines artificial intelligence agents and review by regulatory experts, at a fixed price and on defined timelines. Founded in 2026, it is part of the portfolio of ZNEXT, the industrial platform launched on the initiative of Zanichelli Holding. For more information: www.ardeevo.eu

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Submission-ready. Expert-reviewed.*From regulation to market, on defined timelines and at fixed cost.***MISSION** Healthcare innovation must reach patients, not stop at regulation.**FOUNDERS****Giovanni Stracquadaneo**

CEO and co-founder

Trained in law, with a master's in Lean Healthcare Management (University of Siena), he is adjunct professor of Management and Innovation in Health and Social Services at Università Cattolica del

Sacro Cuore. A serial entrepreneur, he co-founded GenomeUp, a genomic AI startup in healthcare, and has led IVDR compliance programmes and ISO 13485 and ISO 27001 certifications.

**Alessandro Santopaolo**

CTO and co-founder

An engineer and PhD candidate in AI & Automation at Sapienza University of Rome. From 2022 to 2025 he was a Researcher and Innovation Specialist at Leonardo, working on applied AI and

autonomous systems; previously he worked on robotics and AI at the Italian Institute of Technology and at Wandercraft, on exoskeletons for rehabilitation.

SERVICES**Ardeevo Regulatory Compass**

Device qualification, classification and regulatory pathway

Ardeevo Technical File Readiness

Technical documentation, evidence, consistency of the technical file

Ardeevo Lifecycle Compliance

Monitoring, impact of changes, post-market surveillance

The offer is completed by services for the Quality Management System (QMS).

The technical documentation remains drawn up and controlled by the manufacturer; conformity assessment is the responsibility of the Notified Body.

ARDEEVO AT A GLANCE**Company**

Ardeevo S.r.l.

Registered office

Viale della Grande Muraglia
498, Rome

Incorporated

October 2026

Founders

Giovanni Stracquadaneo
(CEO) · Alessandro
Santopaolo (CTO)

Sector

RegTech · AI-native
regulatory services for
MedTech (MDR · IVDR)

Services

Regulatory Compass ·
Technical File Readiness ·
Lifecycle Compliance ·
Quality Management
System (QMS) services

Co-founder and investor

ZNEXT (Zanichelli Holding)
· €150,000 pre-seed
investment · www.znext.io

Websitewww.ardeevo.eu

KEY FIGURES

106,475

medical device and IVD families on the EU market subject to the MDR and IVDR

EUDAMED, 05/2026

52

Notified Bodies designated under the MDR (19 under the IVDR)

European Commission, 20th Notified Body survey, data as of 28/02/2026

90%

of companies in the sector are startups and SMEs

MedTech Europe, Facts & Figures 2025

around €170bn

value of the European medical and diagnostic technology market (2024), 26.4% of the global total

MedTech Europe, Facts & Figures 2025

65%

of MDR technical files submitted to Notified Bodies lack at least half of the required information

Team-NB, 2026

around €22bn

MDR and IVDR compliance spending by 2033

Ardeevo estimates

REGULATORY CONTEXT

The MDR (Regulation (EU) 2017/745) and the IVDR (Regulation (EU) 2017/746), applicable since 2021 and 2022, replaced the previous directives. The transitional periods, extended by Regulations (EU) 2023/607 and 2024/1860, expire **between 2027 and 2029** depending on the device class (Regulation (EU) 2017/745, Art. 120; Regulation (EU) 2017/746, Art. 110). Since December 2025, a **targeted revision** proposed by the European Commission has been under examination by the European Parliament and the Council of the EU. Further rules apply to the same products: the **AI Act** (Regulation (EU) 2024/1689), the **GDPR** (Regulation (EU) 2016/679) and the **NIS2 Directive** (Directive (EU) 2022/2555). Meanwhile, Notified Body staff have fallen by 8% among in-house personnel and by 21% among subcontractors (Team-NB, 2026). In a survey of 267 companies in Germany, Austria and Switzerland, 40% of manufacturers say they no longer place new products on the EU market (BVMed, MedicalMountains, SPECTARIS, VDPH, 2025).

NEXT STEPS

Ardeevo plans to make all its services available by 2027. Over the coming months the services will be activated in stages, reserved for the companies selected for the beta testing programme. The first segment served is manufacturers of medium-risk devices (MDR classes IIa and IIb, IVDR classes B and C): European startups and SMEs seeking their first CE marking, and non-EU companies entering the European market.

PRESS CONTACTS

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