Press Kit

Extra Horizon

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Press Kit
FEBRUARY 2021

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I. Driving the digital health revolution: the vision of Extra Horizon

The future of healthcare is digital. Few people would disagree with that. But companies that develop digital health solutions face significant obstacles when bringing their concept to technological readiness, and their product to market. This is where Extra Horizon steps in. Offering the medically compliant backend that is powering the digital health solutions of the future. Extra Horizon offers a complete à la carte menu of modules and services that can be used to create a fully customised platform for virtually any digital health product or solution. Unleashing the full power of cloud connectivity while taking over the administrative burden and investment risk of guaranteeing regulatory compliance in a complex medical device landscape. In so doing, Extra Horizon plays a role in boosting efficiency, accelerating development and driving the digital transition of healthcare further.

www.extrahorizon.com
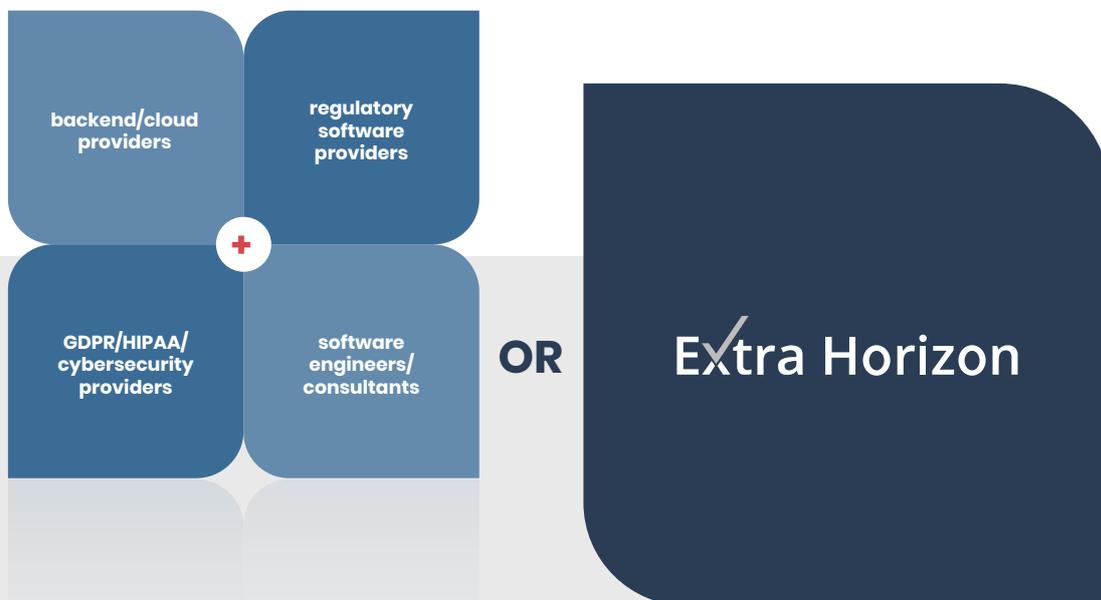
II. **The Extra Horizon story**
A. Strong foundations

Extra Horizon is a fully independent business unit of the digital health company, Qompium based in Hasselt, Belgium. Created in 2018 and launched commercially in 2020, its mission is to drive the digital transition of the healthcare industry by placing Qompium's revolutionary medical platform and cloud infrastructure at the disposal of ground-breaking medical apps and third-party eHealth software developers.

First put into action as the engine behind FibriCheck's innovative heart rhythm monitoring solution, the Extra Horizon platform has since developed into a fully mature solution. After several years of solving the challenges FibriCheck faced, other users of Extra Horizon's innovative medical backend can now be assured of a fully market-proven platform.

Today, Extra Horizon has already begun to disrupt the digital health space. By supplying the **agility, global regulatory compliance and scalability** the industry needs to move forward. As well as a full suite of essential functionalities and associated services. That is how Extra Horizon is driving the digital transition and reshaping the future of healthcare.
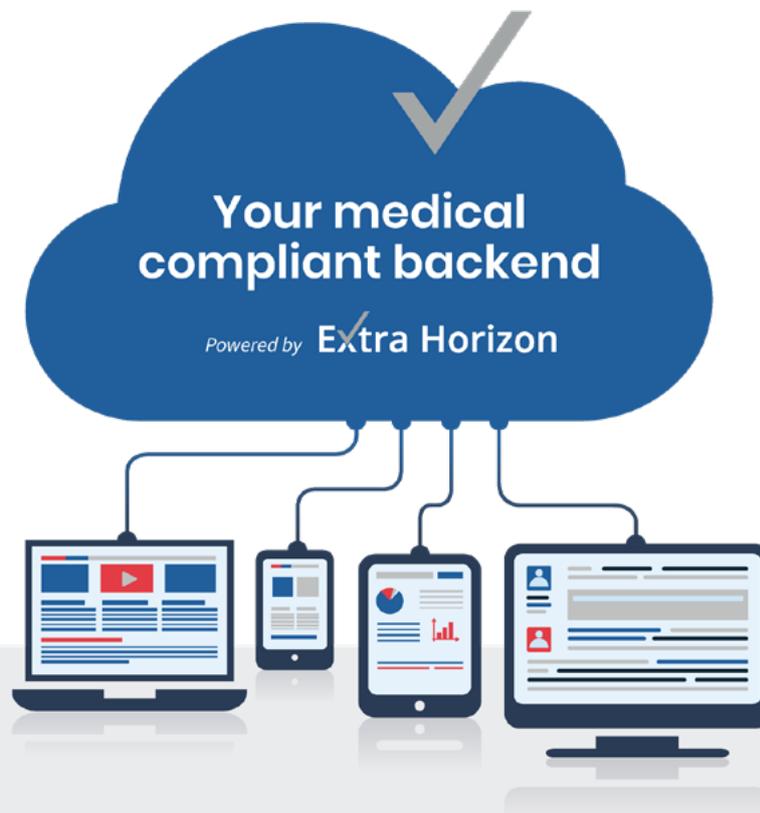
II. **The Extra Horizon story**
B. Powerful solution

The digital health revolution is here. And Extra Horizon is driving it forward! By lowering the barriers for digital health technologies to enter what is a highly regulated market. And enabling them to centralise their critical processes – and the associated liability! – in the cloud, rather than on individual smartphones or other devices.

This medical backend as a service model is a huge leap forward. In the past, developers of digital health products and technologies would have to take care of the entire product cycle from hardware to mobile application, algorithm and cloud infrastructure – essentially reinventing the wheel in the process.

Now, Extra Horizon takes over much of the administrative, technical and regulatory burden by offering the essential cloud infrastructure as a service.
This has several advantages. For one, it ensures full security, privacy and regulatory compliance. It also greatly accelerates time-to-market, allowing users to achieve market readiness up to 80% faster. Most importantly, however, it ensures technology companies can focus their efforts and spend resources on their product – where they own the intellectual property rights! – rather than the surrounding infrastructure.
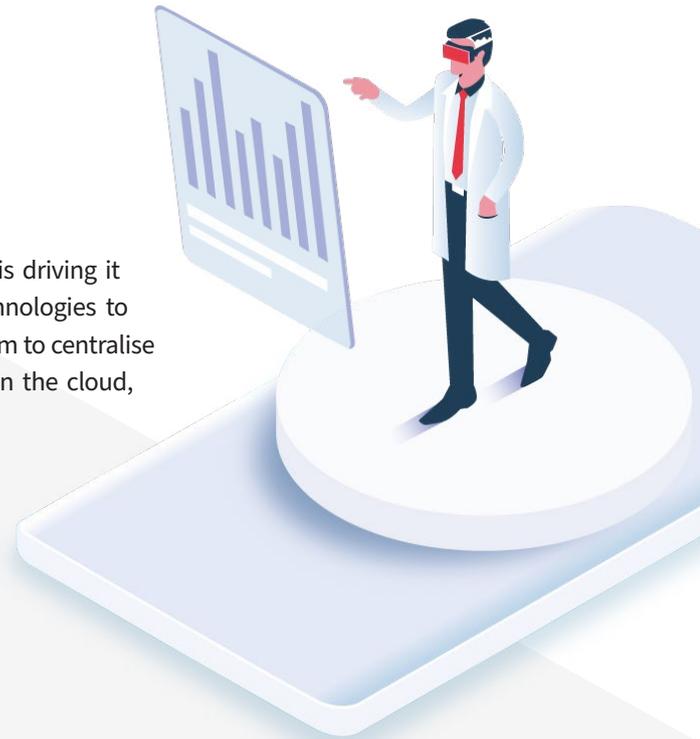
Fast Development	**Security & GDPR**	**Regulatory compliance**	**Customizable**	**Access to experts**
Extra Horizon allows you to **completely develop your back-end in a few weeks** and make additions or changes in hours.	Extra Horizon is a data processor and **provides all necessary GDPR related requirements** and documentation **for your organization**, including cybersecurity.	The individual software services **meet the requirements for medical software** according to **IEC 62304** and Extra Horizon acts as a supplier in your QMS.	You are able to **define your own data structures** using object based programming (NoSQL). All microservices are API controlled and custom tasks can be created.	Extra Horizon is **your single source of information** needed to develop future-proof medical software and to obtain regulatory compliance.

II. **The Extra Horizon story**
## C. Flexible process

Onboarding Extra Horizon is very straightforward. Based on an analysis of the client's current and future needs, Extra Horizon organises a deep-dive workshop to align on the technical requirements and demonstrate the added value of the infrastructure. The deployment process can then begin, setting up the environment based on sprints, which enables an efficient synchronisation with the client's (internal and external) development capabilities. The result is a fully documented API which the customer can submit for regulatory approval. Extra Horizon provides the necessary quality assurance agreements and documentation for the client's infrastructure which remains on a private network and as such, serves as a true core component of the client's product.

Exec. Briefing	Technology assessment workshop*	Production trial	Production ready medical application
1-2 hours	2-3 days	8-12 weeks	3-6 months
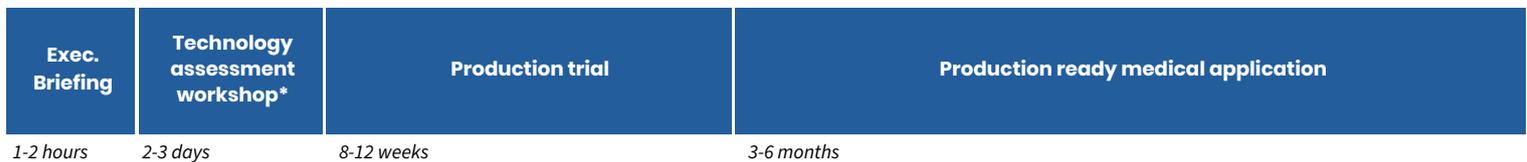
The platform's scalability has already been fully demonstrated, with several start-ups, scale-ups and even established blue chip companies amongst its use cases. This in turn ensures a mature, flexible and fully scalable solution capable of processing, aggregating and sharing extremely large amounts of data, across geographic regions with full security and compliance.

D. Modular framework

The Extra Horizon solution is a truly device agnostic solution, based on modular building blocks which can be combined to create a fully customised solution:

Extra Horizon
Service Overview

Documents	Mail	Translations
Files	Notifications	Webhooks
Tasks	Text Messages	Events
Templates	Payments	Support
Users	Compliance	
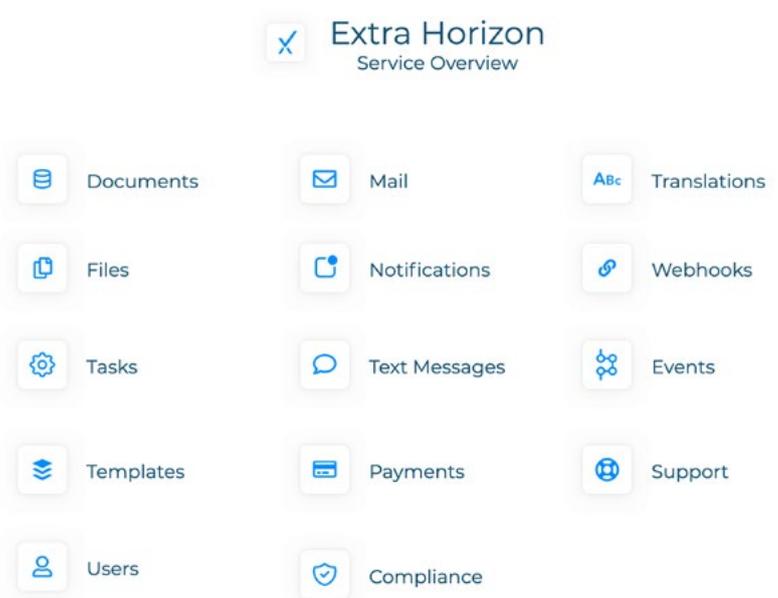
II. **The Extra Horizon story**
   E. Certified, verified and compliant

One of the biggest benefits of Extra Horizon's platform is in the area of regulatory compliance. As well as undergoing independent security, privacy and compliance audits, the platform is also certified under numerous global standards. Most importantly, however, Extra Horizon helps its clients achieve compliance themselves by sharing information, best practices and documentation.

As part of Qompium, Extra Horizon has a proven track record in regulatory and quality affairs with various European (CE Class I and Class IIa) approvals, FDA 510(k) clearances and Australian TGA clearances under its belt. Qompium's medical quality management system (ISO13485 and 21 CFR part 11) ensures high-quality manufacturing of software components for medical use and full compliance with the IEC-62304 medical software and ISO14971 risk management standards.

The Extra Horizon platform is also certified to store and process medical data through ISO27001 information security management and the extended ISO27701 privacy information management standards.

ISO 13485:2016

Certified for medical device quality management systems

IEC/ISO 62304:2015

Compliance to Medical Device software life cycle processes

IEC/ISO 27001:2013

Certified for managing information security risks

IEC/ISO 27701:2019

Certified for managing privacy security risks

GDPR

Extra Horizon is GDPR compliant

HIPAA

Protecting health information

Extra Horizon customers have achieved FDA approvals

Extra Horizon customers have achieved CE Class I and Class IIa approvals

Extra Horizon customers have achieved Australian TGA approvals

II. **The Extra Horizon story**
F. Tailored service models

Whether it be digital health solution providers, manufacturers of medical devices or diagnostics equipment or pharmaceutical companies, Extra Horizon's scalable platform paves the way for a number of equally flexible service models. These range from modular, customisable APIs available "off the shelf" – ideal for companies with their own in-house engineering team – to a complete package of backend and/or front-end services – ideal for companies with a light-weight team that want to move quickly. This flexible approach ensures a perfect fit between Extra Horizon and the client's organisation, no matter the size, domain or approach. As such, Extra Horizon's software expertise is the "skeleton key" that unlocks the ability of a broad range of devices and technologies to enter the digital health space.

⦀ Use cases: Extra Horizon in the field

Extra Horizon's medical platform has been proven to add value in a range of different contexts and for multiple client organisations: from digital health solution providers to manufacturers of medical devices and medical diagnostics equipment and even pharmaceutical companies. The following use cases, with several others already in the pipeline, demonstrate this added value in the clearest way possible.

A. ams chooses Extra Horizon to power innovative point-of-care sensor solutions

ams is the leading worldwide supplier of innovative sensor solutions in the field of in-vitro diagnostics. The combination of its highly advanced optical hardware and Extra Horizon's secure, reliable and medically compliant cloud connectivity services has resulted in a fully connected sensor solution which enables extremely fast, accurate and efficient lateral flow tests including SARS-CoV-2 antibody digital rapid tests.

Pierre Laboisse, Executive Vice President Global Sales and Marketing, ams.

"Governments and authorities need to enable fast, reliable and effective testing with the results available through a fast, secure and GDPR compliant medical-grade cloud solution. Extra Horizon offers best-in-class medical cloud solutions through their deeply proven expertise in medical cloud. Their professional expertise in developing customized solutions, leveraging their extensive backbone knowledge, makes them an ideal partner for this important undertaking. We hope that this solution will eliminate complicated logistics and clinical processes and streamline approaches to mass testing and effectively become an essential tool in the effort to help control the pandemic and resume the many economic and social activities that comprise what we call normal life."

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Lars Grieten, CEO Extra Horizon:

"This project is a powerful demonstration of how state-of-the-art health tech sensors can be enhanced with digital infrastructure to deliver point-of-care testing solutions both in the professional and home environment. Rapid testing will become more relevant in our digitised future. And by enabling critical decisions to be taken faster, it is already providing much needed support for managing the COVID-19 crisis."

Read more about the strategic partnership between ams and Extra Horizon >

⦀ Use cases: Extra Horizon in the field

B . FibriCheck:
world's first medically approved heart rhythm app

Used in over 43 countries worldwide and totalling over 450,000 users, FibriCheck is a textbook demonstration of the power of digital health solutions, particularly in the contexts of the current COVID-19 pandemic. Using the built-in PPG sensor found, e.g., in smartphones and smart watches, the Extra Horizon platform enables FibriCheck to convert a range of consumer devices into fully certified medical devices for the detection of heart rhythm disorders such as atrial fibrillation. In particular the backend's centralised control structure enables FibriCheck's medically approved algorithm to be deployed across all users simultaneously, scaling capacity to meet acute user load on demand. Most importantly, it does so while ensuring full compliance with strict privacy and cybersecurity standards in multiple geographical regions.

Particularly during the pandemic, the remote monitoring capability of the FibriCheck app is proving to be a vital tool in securing the continuity of care while safeguarding the health and safety of patients and healthcare professionals.

Kobe Leysen, CTO FibriCheck.

"When we started with FibriCheck, we learned the hard way that in-house development of solutions is a very costly experience. You need to find the right people with the right expertise and spend a lot of your resources and time to develop. That made it easy to reconsider our strategy and flip to Extra Horizon. Since then, our company has only thrived and we've been growing month by month, while having total peace of mind."
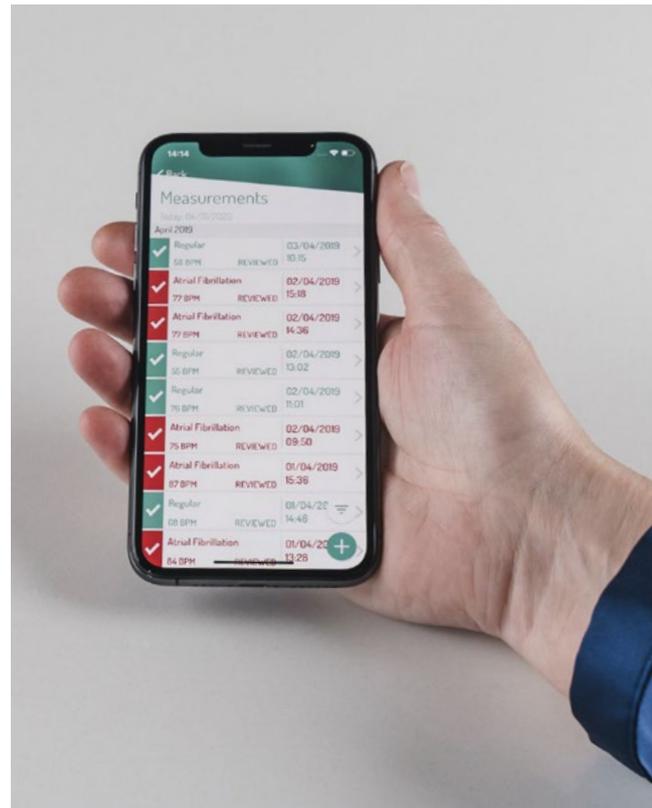
Read more about the revolutionary technology that is driving the FibriCheck success story >

IV Shaping the future of healthcare:
the role of Extra Horizon

The COVID-19 pandemic has clearly demonstrated the urgent need for the rapid development, deployment and integration of digital healthcare solutions. Solutions that harness the full power of cloud connectivity to deliver high-quality, effective, efficient care. While protecting the safety of patients and healthcare professionals alike.

However, companies who develop the medical software needed to support medical devices and algorithms face a number of complex hurdles. Not least of which, they need to comply with strict regulatory requirements such as those imposed by CE and the FDA. And then there's the complex legislative landscape of GDPR, HIPAA and other data security and privacy regulations governing the processing of sensitive patient records and medical data. Little wonder that of the more than 2.2 million medical apps already out there, only around 160 have actually been approved by the FDA.

And that is precisely where Extra Horizon steps in. Extra Horizon provides the industry with a mature, agile, powerful and globally compatible engine with the proven ability to drive practically any kind of medical software application. From solutions in the area of respiratory diseases and cardiology to in-vitro diagnostics, Extra Horizon services products that offer both back and front-end solutions and for direct-to-consumer and business-to-business use cases.

In this sense, Extra Horizon acts as an enabler of the digital transition, providing companies with the tools, infrastructure and knowhow they need to bring their eHealth solutions to market faster and with greater impact. By supplying its medical backend as a service, Extra Horizon accelerates the technological readiness of its clients and partners while taking over the burden of regulatory complexities and de-risking their investment.

∨ **Milestones**

AUGUST 2014

Qompium is founded

2014 - 2017

Development begins on FibriCheck, a mobile application that detects cardiac arrhythmias using only consumer devices such as smartphones

JUNE 2016

Qompium achieves ISO13485 certification

JULY 2016

FibriCheck and its medical cloud infrastructure obtain medical device Class IIa approval in Europe

AUGUST 2018

Extra Horizon is created as an independent business unit within Qompium

SEPTEMBER 2018

First digital health solution powered by Extra Horizon receives FDA 510(k) approval

JUNE 2020

Australia's TGA grants approval for FibriCheck app using Extra Horizon's infrastructure

JULY 2020

Commercial launch of Extra Horizon as a scalable medical backend-as-a-service platform enabling other groundbreaking medical apps to join the digital health revolution faster

DECEMBER 2020

Qompium achieves ISO27001 and ISO27701 certification for both its FibriCheck and Extra Horizon business units

JANUARY 2021

Extra Horizon forms strategic partnership with ams to develop in-vitro diagnostics (IVD) solutions in the fight against COVID-19

VI **Who is Extra Horizon?**
A. The team

Qompium was founded in 2014 by Lars Grieten, Kobe Leysen, Bieke Van Gorp and Jo Van der Auwera. While working on FibriCheck - Qompium's certified mobile app for detecting cardiac arrhythmias - the four garnered a great deal of inside knowledge, experience and insight about the development of medical applications, which they now place at the disposal of other digital health companies through the medical platform, Extra Horizon.

Extra Horizon was launched as an independent business unit in August 2018. Today, its talented team of 26 employees from diverse fields such as technology, regulatory, quality, clinical research and commerce is committed to shaping the future of the healthcare sector.

B. The founders

Kobe Leysen, CTO   **Bieke Van Gorp**, CBDO   **Lars Grieten**, CEO   **Jo Van der Auwera**, CRO

Lars Grieten, CEO

Armed with a PhD in biomedical sciences, Lars began working at the East-Limburg Hospital in 2012 as project manager for the Limburg Clinical Research Programme. It is there that he founded the Future Health department where he and his team investigated and developed a range of digital health solutions. In 2013, Lars became senior researcher at imec, Europe's largest research centre for micro-electronics and digital technology and in 2015, was guest professor of digital health at Hasselt University. Lars co-founded Qompium in 2014. Under his wings, FibriCheck became a pioneer in digital health as well as an established and successful brand. Building on trust and clinical credibility, its user base soon grew to over 450,000. Lars is a much sought-after motivator and public speaker with an extensive network in both the digital health and clinical landscape. Lars has gained a significant understanding of the inner workings and requirements to deliver digital health solutions and utilises this knowledge to offer solutions to Extra Horizon customers.

Bieke Van Gorp, CBDO

After completing her Master of Business Administration at the Catholic University of Leuven and a Master in Finance at the Labovitz School of Business and Economics, Bieke began a career in Mergers & Acquisitions at BNP Paribas Fortis in Brussels, Amsterdam, Paris and New York. She later worked at Pomin (owner of several different Belgian companies) as direct strategic advisor where she was responsible for Mergers & Acquisitions and special projects. Over the past 7 years, Bieke has built up extensive experience in the digital health space, pioneering with FibriCheck. Responsible for business and marketing, Bieke has successfully rolled-out various business models, including multiple collaborations with international blue chip companies, reimbursement tracks and a successful B2C model. Within Extra Horizon, Bieke applies her experience and strategic expertise to support the smooth roll-out of the business unit's service platform. Bieke is in high demand as a public speaker with an extensive network in the field of digital health.

Jo Van der Auwera, CRO

Jo has a Master of Science in biomedical sciences from Hasselt University with majors in bio-electronics and nanotechnology. As a clinical researcher at East-Limburg Hospital, he worked on remote patient monitoring and disease management in patients with an implantable cardiac device. Since the launch of Qompium, he has been responsible for regulatory quality control and compliance. Jo is a highly sought-after expert in the medical approval of mHealth applications and was instrumental in obtaining FDA, TGA and CE approval for FibriCheck, one of the first apps to be powered by Extra Horizon's medical platform.

Kobe Leysen, CTO

Kobe has a Master of Science in Industrial Engineering and is specialised in Computer Engineering. As co-founder of Qompium, he architected and designed the entire software infrastructure behind FibriCheck, resulting in a scalable and flexible backend that supports over 450,000 users. Thanks to the experience he gained with FibriCheck, Kobe has become well versed in agile medical software development and an expert in architecting and designing future-proof cloud infrastructure capable of adapting to the constantly evolving digital health space. At Extra Horizon, Kobe heads a very effective team of 11 developers and data scientists.

VI **Who is Extra Horizon?**
C. About Qompium

Qompium is a healthtech company dedicated to driving the digital transition and fostering innovation in the global healthcare industry. Founded in 2014 and based in Hasselt, Belgium, Qompium comprises two independent business units: FibriCheck – the fully certified smartphone and smartwatch app capable of detecting and managing heart arrhythmias – and Extra Horizon – the platform that provides third-party medical applications with a powerful, secure and fully compliant backend. Qompium currently employs around 30 people and has strong ties to the medical world through an extensive network of researchers, clinicians, practitioners and other healthcare professionals.

D. Extra links

LinkedIn
Website
Press room

VII **Media contacts**

Spokespersons

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