

## **RDS secures CE mark for MultiSense® Remote Patient Monitoring solution**

- **European certification marks next step on path to marketing medical device in Europe**
- **Company prepares Series A funding round in 2024 to support commercialization and development work**

**Strasbourg, France, March 5, 2024** – RDS, the medical device start-up, today announces the granting of the CE mark for MultiSense®, its patented, wearable solution for continuous Remote Patient Monitoring. This class IIa medical device certification, in compliance with Regulation (EU) 2017/745, is a major regulatory milestone for the company.

“Achieving this pivotal milestone is testament to the hard work of our technical development teams in recent years – working in close collaboration with the RDS department for quality assurance and regulatory affairs – alongside the many other teams and partners involved in developing this device,” said Stéphanie Hilbold, director of quality assurance and regulatory affairs at RDS. “It demonstrates our company’s ongoing commitment to innovation and excellence in the field of medical technology.”

MultiSense is a Remote Patient Monitoring device comprised of a wearable electronic patch, a secure online platform and associated support services. The current version allows healthcare professionals to remotely monitor six physiological parameters – heart rate, respiratory rate, oxygen saturation, skin temperature, patients’ level of activity and body posture – in real-time - to the same standard as a clinical monitoring system. The device has been tested in six clinical trials.

The patch features five miniaturized biosensors, a patented adhesive layer and a battery pack with enough capacity to monitor patients’ vital signs for at least five days. It is supplied as a ‘ready-to-use’ kit and most of the components can be refurbished and reused, increasing the device’s sustainability and minimizing its carbon footprint.

The MultiSense platform is a secure cloud interface that gives healthcare professionals remote access to their patient monitoring data. It features several different dashboards for visualizing patients’ vital signs and various notification features to identify situations where clinical action may be required. The platform complies with GDPR requirements and is hosted by a health data hosting provider with HDS certification.

By enabling the remote monitoring of patients’ vital signs, MultiSense helps medical teams improve the quality of life for patients both in hospital and at home. The solution supports an innovative new technological and organizational approach that is transforming care pathways, notably by allowing post-surgery patients to be discharged from hospital sooner and adhering to the principles of Enhanced Recovery After Surgery or ERAS.

“The CE mark represents another important step on the path to marketing our solution in Europe,” said Elie Lobel, CEO of RDS. “We’ve already begun the pre-commercialization phase; the initial results are very positive. Clinicians have shown a keen interest in our device and its potential to transform patient pathways.”

Most interestingly, the MultiSense solution has been selected for use in several innovative projects, including a hospital-university research program (RHU) run by Amiens-Picardie University Hospital and an innovation program in oncology (Tiers Lieu d'Expérimentation Onco-Atlantique) headed up by three major cancer centers in Nantes, Angers and Bordeaux, France and the Hospital of Mont-de-Marsan, France.

This year, the company also plans to launch a Series A funding round to support the marketing of MultiSense across Europe, to continue the company's product development work, launch new clinical trials and register the product with the US authorities ready for its release in the United States, which is planned for 2025. The [global market for remote patient monitoring](#) was valued at around \$53.6 billion (€49.5bn) in 2022, with an average annual growth rate of 26.7% forecast for the period from 2022 to 2027.

### **About RDS**

RDS develops and markets MultiSense®, a next-generation Remote Patient Monitoring (RPM) solution. This comprises a wearable electronic patch for collecting clinical-grade, real-time, physiological data - both in hospital and at home - and a secure cloud platform that enables healthcare professionals to access this data as part of their remote patient monitoring programs. MultiSense is protected by more than 20 patents and has been validated in six clinical trials.

RDS relies on its talented international team and has received numerous accolades, including the i-Lab prize in 2020, the Grand Prix de l'Académie des Technologies in 2022 and the i-Nov award in 2023.

The company was founded in 2020 and is based in Strasbourg, France. It is incubated at SEMIA/Quest for Health and is part of the Future4Care accelerator program. It currently employs around 20 staff.

[www.rdsdiag.com](http://www.rdsdiag.com)

MultiSense® is a class IIa non-reimbursable medical device manufactured and marketed by RDS SAS. It is a regulated healthcare product and carries a CE mark in accordance with Regulation (EU) 2017/745 (notified body: Eurofins Product Testing Italy S.r.l., no. 0477). Further information about the device can be found in the instructions for use.

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