Case Study

Helping patient monitoring manufacturers innovate safely

Sidly

UL Solutions

Safety. Science. Transformation.™

Successfully introducing on the market an advanced medical wearable device

Sidly Care Pro wristband is a medical monitoring device with a wide range of functionalities used in the field of home patient care.

Regular measurements of illustrative heart rate and saturation values

Possibility to set a notification on the platform when limit values are exceeded.

Fall and immobility detector

Automatic notification on the platform about the loss of consciousness by the patient.

SOS emergency button

Tactile button marked with Braille, allowing you to send a notification to the platform.

GPS and aGPS location of the user

It allows the user's location and setting the so-called safe area.

Brand attachment sensor

Sends a notification to the platform when the wristband is removed or incorrectly put on.

Two-way voice communication

Ability to program trusted numbers that can call the wristband.

Medication reminder

Message in polish, reminding about the time of taking medication when the patient is at home.

Voice assistant

Infoming the user about pressing the SOS button, starting, charging and discharging the band. Choice of language.

Benefits for the hospital of using the Sidly care pro telemedicine system

- Effective control of the patient's health before and after the procedure, which relieves the health care system.
- Positive impact on the prognosis of the patients requiring home rehabilitation.
- Facilitating the diagnostic process and shortening its time, with measurable clinical benefits. Support for secondary prevention.
- Fewer in-patient visits while regularly monitoring patient parameters.
- Enabling better cooperation in the therapeutic team and control of the pharmacological treatment process.
- Reducing the costs of hospitalization resulting from too late diagnosis of the patient's condition.

Introduction

SiDLY, one of the fastest scaling companies in the deep tech segment, was created out of the need of the company founder and president, Edyta Kocyk, to take care of her grandmother who fell ill with dementia in 2014. Together with cofounder and vice president of the board, Michał Pizon, they created a telemedicine wristband that was initially only for the use of Kocyk's loved ones. They quickly realized, however, that many people had loved ones with similar needs and commercialized and developed the project for the Polish and European Union markets. Nearly a decade later, SiDLY is a team of over 100 people who develop telecare services with passion and care.

In 2022, the number of people covered by modern wearable technology increased to over 25,500. The product includes a data analysis system and is supported by a medical Telecare Center at which the work of medical staff is supported by systems based on artificial intelligence.

In 2023 SiDLY has received the status of a professional medical device class IIa. From now on, patients can benefit from 24/7 health monitoring via the SiDLY wristband. This is a big progress in the area of health care, quality of life, patient care and also senior care. This provides a number of opportunities for a new quality in health care.

Challenge

To validate and verify the accuracy and performance of their telemedical device, Sidly Care Pro, the company worked with UL Solutions. They wanted to ensure that the product met the required standards for pulse and saturation measurement in ISO 80601-2-61. SiDLY knew that achieving UL Certification would demonstrate to the market that the device met the necessary requirements specified in ISO 80601-2-61 and would differentiate it among discriminating consumers. Additionally, obtaining this certification was a condition for achieving the status of a professional medical device class IIa.

According to Edyta Kocyk, "the specific challenge we faced with our product was to ensure that it met the highest standards of quality and certification. Given that SiDLY Care Pro is relied upon daily by our medical rescuers to provide vital information and guidance to users, it was essential for us to achieve accurate and reliable measurements of pulse and saturation levels. This required developing a solution that could perform consistently and accurately, even in challenging environments or during physical activity."

During the testing process, UL Solutions' assistance was valuable in addressing SiDLY's doubts and providing guidance. The company was eager to ensure that its device performed reliably and accurately in measuring pulse and saturation levels — critical parameters for medical monitoring. **"By achieving compliance with ISO 80601-2-61 and obtaining UL Solutions' approval," said Edyta Kocyk, "we aimed to demonstrate the quality and safety of our telemedical device to both regulatory bodies and potential customers. UL Solutions' expertise and support were instrumental in helping us navigate the testing process and ensuring that our device met the necessary standards."**

SiDLY Care Pro presented specific challenges due to its critical role in saving lives. Specifically, Sidly Care Pro is a wearable device able to detect falls and automatically contact a caregiver if immobility is observed after the fall. The device works like a 2G phone with two-way voice communication through a built-in speaker and microphone. The wearer's position, whether indoors or outdoors, can be located thanks to an internal GPS feature. It also measures the wearer's heart rate and reminds them of their medication schedule with a voice assistant. The device's capability to accurately measure pulse and saturation levels is of utmost importance for providing reliable data that medical rescuers can base their assessments and advice on. This sets the product apart from others in the market, as it combines advanced telemedical technology with the life-saving capabilities of real-time monitoring through a radio transmitter using 2G bands with a SIM card, as well as Wi-FI when available.

Additionally, being one of the few companies in Europe that develops its own solutions for pulse and saturation measurements further highlighted the uniqueness of the product. By creating proprietary technology, SiDLY has the advantage of tailoring the device's performance to meet the specific requirements and standards of the telemedical industry. This demonstrated their commitment to innovation and enabled them to provide a cutting-edge solution that set them apart from competitors.

"Overall, our product's ability to save lives, the reliance placed on its measurements by our medical rescuers, and the development of our own pulse and saturation measurement solutions make SiDLY Care Pro special," said Michał Pizon. "The challenges of achieving the highest quality standards and certifications highlight our commitment to ensuring the device's accuracy, reliability and effectiveness in critical healthcare situations."

Solution

UL Solutions provided extensive support throughout the engagement with SiDLY.

> **“They assisted us in various aspects related to the ISO 80601-2-61 testing and certification process for our telemedical device,” said Edyta Kocyk. “Their support included pre-compliance testing, certification, and more.”**

This support included pre-compliance testing. UL Solutions advised SiDLY to conduct a preliminary investigation that allowed them to identify areas that needed improvement and provided them with valuable insights into critical aspects to focus on. The preliminary investigation was a prudent decision that helped SiDLY save time and resources.

> **“UL Solutions played a crucial role in the certification process,” said Edyta Kocyk. “They carefully examined our solutions, reviewed documentation and records, and conducted necessary tests. This comprehensive evaluation helped ensure that our device met the required standards and received certification, signifying its compliance with ISO 80601-2-61.”**

Throughout the testing and certification process, UL Solutions’ experts were readily available to address SiDLY’s doubts and provide guidance. The team reviewed documents and records, collaborated with SiDLY during on-site visits, and offered valuable advice for future improvements. This support helped the company ensure that all aspects of ISO 80601-2-61 were thoroughly assessed and met, enhancing the product’s quality and compliance.

Conclusion

> "Overall, UL Solutions provided valuable support in testing, pre-compliance testing, certification, and guidance," added Michał Pizon. "Their expertise, attention to detail and collaboration significantly contributed to the successful completion of the testing process for our telemedical device, SiDLY Care Pro."
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> "We had a highly fruitful and collaborative experience working with UL Solutions and the laboratory during the testing process for ISO 80601-2-61," said Kocyk. "The collaboration was characterized by open communication, valuable assistance, and a strong focus on achieving our goals."

The preliminary investigation recommended by UL Solutions allowed SiDLY to identify areas for improvement and gave them valuable insights into critical aspects. This approach saved the company a significant amount of time and resources while highlighting important considerations.

> "Throughout the entire process, UL Solutions' team demonstrated great attention to detail and provided us with prompt support whenever we had doubts or uncertainties," said Edyta Kocyk. "They were responsive to our questions, resolving our concerns and providing us with valuable advice for future improvements."

SiDLY has successfully obtained positive test results for the device according to ISO 80601-2-61. As a result, SiDLY Care PRO has been recently certified as class IIa medical device and it is the first wrist-worn telecare device certified according to MDR. **"Obtaining confirmation of compliance with ISO 80601-2-61 has generated interest among potential buyers of our wristband," said Edyta Kocyk. "This confirmation reinforces the accuracy of our measurements and the high quality of our device. And when clients ask about standard compliance, we can proudly confirm that we pass it."**

If you would like to learn more about how we can help you test and certify your medical devices, please visit UL.com/medical-device-testing or contact us at UL.com/contact-us

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