Nicholas Hall's CHC INSIGHT EUROPE

Serrix Consumer Health: The journey to Rule 21 MDR Certification

In 2021, the new European legal framework for medical devices – The Medical Devices Regulation (MDR) – came into effect (transitional periods recently extended until 2027 / 2028), replacing the Medical Device Directive (MDD) and comprising new criteria for achieving medical device certification. We talked to Irene Heijmans, Regulatory Affairs / Quality Assurance Manager at Netherlands-based Serrix Consumer Health about the company's recent MDR certification, the journey to transition and advice for other manufacturers.

Transition process

Q: Congratulations on receiving MDR certification for your medical devices! Can you tell us a bit more about the process of MDD to MDR transition?

A: Thank you for your congratulations! Transitioning from MDD to MDR has been a necessary journey for Serrix, and we are thrilled to have achieved certification for our substance-based medical devices **Mycosan** (nail antifungal), **Sorefix** (cold sore treatment) and **donttellmum Eczema Repair**.

The transition reflects our commitment to delivering safe and effective products to consumers while conforming to the latest regulatory standards, and has been a comprehensive and strategic undertaking. We began preparations in 2017, when we first became aware of MDR, learning and thoroughly understanding the differences between MDD and MDR. As we now know, there are many differences, including the incorporation of Unique Device Identification, Clinical Data Enhancement, Post Market Surveillance and more.

Throughout the transition, we remained dedicated to providing high-quality products and upholding the trust that our consumers and partners place in us. Our successful MDR certification demonstrates our adaptability and commitment to maintaining the highest standards in the consumer healthcare industry, and we are excited about the opportunities it brings and look forward to continuing to serve our consumers with innovative and safe medical devices.

left: Els Gillis of SGS Benelux presents the MDR Certificate to Irene Heijmans and Ruben Visser of Serrix
right: Mycosan, Sorefix and donttellmum Eczema Repair

Safety & efficacy

Q: How has Serrix ensured the safety and efficacy of its medical device products according to MDR requirements?

A: We conducted rigorous clinical assessments, encompassing trials and literature reviews, with this thorough evaluation guaranteeing that our products are safe. In addition, our commitment to post-market surveillance has been amplified.

We actively and systematically gather, record, and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime. This includes the monitoring of post-launch device performance much more closely, promptly addressing any emerging safety concerns, and maintaining transparent communication with regulatory bodies, HCPs, and consumers; this is the cornerstone of our approach, and sharing information helps maintain trust and awareness. Fortunately, our incident rate under MDD was already very low, negligible even, and with MDR this will remain the case.

Impact

Q: What impact do you expect MDR certification to have on your business? Or what impact does it already have?

A: MDR certification has already begun to have a considerable impact on our business, and we anticipate ongoing effects. Our credibility has been bolstered, enabling smoother entry into the market, and certification ensures compliance, positioning our medical devices favourably across the EU. Distributors now have increased confidence in our products, and certification reflects our dedication to safety and effectiveness, reassuring consumers of our commitment to high standards.

While MDR standards are specific to the EU, we nonetheless adhere to them globally in order to enhance our competitiveness; our reputation for meeting robust regulatory requirements strengthens our presence in diverse markets. Overall, MDR certification is already having a positive impact on our business through expanding our market presence, boosting consumer trust, and encouraging innovation and collaboration.

Challenges

Q: Can you tell us about any challenges Serrix faced in obtaining MDR certification and how you have addressed them?

A: The journey towards MDR certification was marked by a series of challenges, each demanding a thoughtful strategy and persistent effort. As we embarked on this transition, we found ourselves grappling with the intricate web of regulatory changes that MDR required.

The largest hurdle arose from the need to reevaluate the classification of our devices. Under the new classification Rule 21 of the MDR (and related MDCG guidance on classification rules), many substance-based medical devices require reclassification i.e. they are classified in a different risk category than they were previously. We undertook a meticulous review of our device classifications, ensuring that our strategies and approaches matched the revised criteria. This attention to detail was pivotal in guaranteeing a seamless transition, although it was also very challenging.

Advice on transition

Q: Finally, what advice would you give to companies that have not yet fully transitioned to MDR, and how can they ensure that their medical devices comply with the new regulations?

A: The journey is not without its challenges, but within these lies an opportunity for growth, excellence, and a renewed commitment to delivering the safest and most effective medical devices. A team of dedicated individuals should sit at the heart of transition, who understand that the path to MDR compliance is not simply a regulatory obligation but a chance to set new benchmarks in product safety and efficacy. The story begins with a simple yet resounding piece of advice: start early. Recognizing the magnitude of transition, Serrix took proactive steps, setting in motion a process that would redefine its practices.

The new regulatory landscape is a testament to the delivery of products that stand up to the highest standards during their full lifecycle. The journey does not end here; rather, it moves forward, ready to embrace new horizons, inspire confidence, and continue shaping the future of medical devices.

For further information on Serrix's MDR journey or Serrix products, please contact: info@serrix.com