Jacoti HEARING WITHOUT BARRIERS

Jacoti Achieves MDR Certification – The Strongest Base for High-Quality Consumer Audio Tech

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Jacoti BV, a pioneer in advanced hearing technologies, has received EU Medical Device Regulation (MDR) certification for its Class IIa devices – Jacoti Hearing Center and Jacoti Hearing Center Pro. This important certification underscores the company's commitment to excellence in the quality of its software products and internal processes.

EU-MDR 2017-745

Jacoti's attainment of the MDR certification is an important milestone in the company's mission to revolutionize hearing technologies. This certification uniquely positions Jacoti as being able to provide solutions for those companies wishing to build hearing aid products on cost-effective consumer technology platforms. It also provides the highest quality software to those wishing to offer their customers the ultimate hearing personalization and audio quality in headsets and hearables [1].

Jacoti is strongly committed to excellence in the quality of its software products and internal processes and always strives to achieve the highest standards, as exemplified by the recent MDR certification. To ensure a smooth and timely transition for Jacoti's devices – previously CE marked under the MDD, a comprehensive strategy had been developed to obtain conformance with the MDR requirements.

The European Union (EU) introduced the MDR to modernize and strengthen the EU legislative framework governing medical devices. However, the transition from the previous Medical Device Directive (MDD) to MDR has presented a significant challenge for many manufacturers[2]. Despite these challenges, Jacoti has been successful in obtaining MDR certification[3], highlighting the company's dedication to delivering high-quality products.

Jacoti remains well-positioned to continue its innovation in science-based hearing solutions that meet the needs of consumers and comply with regulatory requirements inside and outside the EU market. With Jacoti Hearing Center leading the way as the first product with MDR certification, Jacoti continues to demonstrate its expertise and leadership in the hearing technology industry.

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[1] Jacoti's processes and products will continue to be audited on a yearly basis to the MDR requirements as well as to Medical Device Quality Management Standard ISO 13485:2016.

[2] Notified Bodies have reported that a majority of manufacturers are late with their submissions or showing an overall lack of preparedness (Notified Body position paper on MDR/IVDR Implementation. The European Association for Medical devices of Notified Bodies)

[3] MDR certificates have not been achieved yet for over 85% of the devices previously certified under the MDD (as of April 2022, MedTech Europe trade association report)

About Jacoti

Jacoti BV | Hearing Technologies is a science-based company that develops hearing enhancement solutions embeddable in consumer devices. Its flagship product, Jacoti Inside, optimizes audio to each individual hearing requirement from consumer technologies to fully-fledged medical devices. For more information visit www.jacoti.com

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