

# Jacoti completes another successful quality audit to new Medical Device Standard ISO 13485:2016

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NEWS · February 27th, 2019

**Jacoti bvba, pioneers of deeply embedded hearing technologies, is delighted to announce the completion of another successful quality audit to the new Medical Device Standard ISO 13485:2016**



Since its inception, Jacoti has made quality and regulatory compliance a priority. As a small company that develops medical standalone software for hearing testing and support, Jacoti was one of the first to implement and achieve certification of a medical grade Quality Management System. Subsequent EC Certification has authorised the company to build and distribute in the EU area hearing solutions based entirely on standalone software.

The company's continuous commitment to understanding and meeting the relevant Regulatory and Quality standards has resulted in the following achievements:

- After 5 years of the first certification, Jacoti's EC Certificate has been renewed and, therefore, the company can continue placing hearing support applications on the market for a further 5 years (2023).
- In 2018, Jacoti has been thoroughly (and successfully) audited against the new and more risk-averse Medical Device Standard ISO 13485:2016. As a result, the company Quality Management System was certified and remains valid until 2022.
- As one of the most critical aspects of the development of a Medical Device, the company has continued to monitor the Clinical Evaluation of its products. In recent years, Jacoti has upgraded all the clinical evaluation documentation to comply with the new and more stringent MEDDEV 2.7.1 revision 4.

Meanwhile the company is continuing its work in developing software-based hearing solutions and ensuring that its products will meet the new Medical Device Regulation that is due to become into force in May 2020. Conformance to all necessary standards and a commitment to quality excellence remains at the centre of all Jacoti activities.

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## **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](http://www.jacoti.com)

Contact our Press Officer for more information or to arrange an interview with our team.

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