

## Novioscan wearable ultrasound care; quality management

Already during the preparation of the market introduction of the first Novioscan product, the SENS-U Kids, Baelde Consulting has been actively involved with Novioscan, first as a consultant in the background and later as an internal auditor. When at the end of 2018 a new management team took over to lead the company to a next phase, it was only natural to ask Baelde Consulting to assume the role of quality manager in the new management team for a year.

The year 2019 was an important year for Novioscan. The new management has deployed a much more active sales strategy, thereby enabling further growth. Baelde Consulting contributed to this through a far-reaching consolidation of the quality system (e.g. improved document management and software validation). In addition, Baelde Consulting has taken on a broader advisory role and has made preparations for the automation of the logistics process to facilitate the rapid growth to be expected.

In addition to consolidating the quality system, it was also necessary to prepare for the implementation of the new European regulation for medical devices that Novioscan products have to be compliant with (EU 2017/745) in 2020. To ensure the smooth application of this regulation within Novioscan Baelde Consulting, in close cooperation with the experts from Novioscan, has made an analysis of the necessary changes to the product, documentation and quality system. As a result, there is a clear action plan that will enable Novioscan to meet the requirements of EU 2017/745 in a timely manner.

In summary, thanks to the active support of Baelde Consulting in 2019, Novioscan is optimally prepared for the next phase of the company's development.



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