



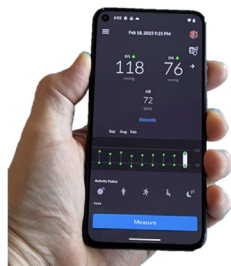
Case Study # 1: Blood-Pressure Measurement App



Client

Biospectral SA

- startup company
- Lausanne
- Developed OptiBP, an app which can optically measure blood pressure using a smart-phone's camera



The Challenge

- For Biospectral, **time-to-market** was crucial.
- However, **they lacked the in-house expertise to establish a Quality Management System (QMS) and obtain ISO 13485 certification for the company**, as well as certification under the Medical Device Regulation (MDR) to launch their product in the EU, Switzerland, and the UK.
- Furthermore, **the MDR's activation had overwhelmed all Notified Bodies**, preventing them from serving Biospectral promptly.



Solution

- Through EM's legal manufacturing service, Biospectral **gained immediate access to Effectum Medical's certified Quality Management System (QMS)** and was able to establish their technical documentation under the expert guidance of EM's specialists.
- This allowed Biospectral to **focus on their core expertise: product development.**

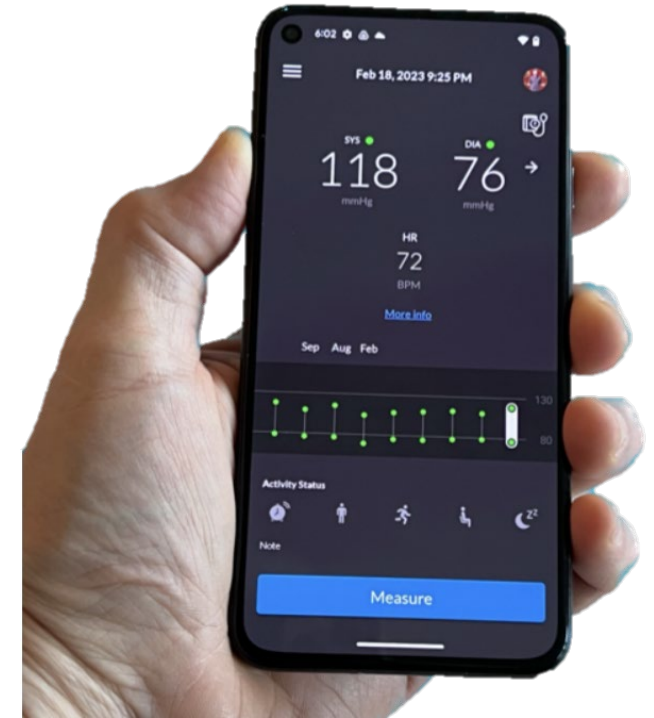


Results

- The technical documentation was established **within nine months**, and **CE certification for OptiBP was obtained within 14 months** after submission.
- OptiBP went **live in January 2024**, with **several hundred licenses sold in this short time**. High growth is expected in the coming months.



- Timely establishment of key deliverables in close collaboration with Biospectal:
 - MDR compliant technical documentation
 - Definition and completion of verification and validation activities
 - Definition and completion of clinical evaluation activities
 - Definition and completion of the risk- and usability-analysis
 - Set-up of key suppliers, including contractual frameworks
 - Definition of post-market reporting and data collection activities
- Handing in the Technical Documentation to the Notified Body and management of all Notified Body interactions up to obtain CE certificate for OptiBP.
- Managing the change control process and communication with Notified Body (on-going)





Key Learnings:

Frederic Frappereau | Head of Product @ Biospectal



- **Successful Navigation in the Regulatory Environment:** Under EM's guidance, we successfully adapted to working under a Quality Management System (QMS) and regulatory environment despite initial inexperience.
- **Mastering Medical Software Documentation:** Embracing the challenges of specialized documentation leads to successful outcomes.
- **Working in an eQMS Brings Clear Benefits:** Enhanced accuracy, efficiency, error reduction, and time savings.
- **Substantial Reduction of Time-to-Market:** Bypassing the establishment of our own Notified Body relationship and delaying internal resource setup enabled faster product delivery.
- **Reimbursement:** Our launch was successful despite not having secured reimbursement yet, as patients are willing to pay out-of-pocket.

