# Bo Esbech

M.Sc. Electrical Engineering, DTU

Medical Device R&D expert

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## medicologic®
### Medical Device Development

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## Competences

- Excellent team leader with ability to provide clarity in complex and multidisciplinary problems.
- Solid technical knowledge in mathematical modelling, software, digital design, sensors, optical and mechanical systems.
- Concept development and testing.
- Deep understanding of regulatory requirements including design controls (ISO 13485), risk management (ISO 14971) and IEC 60601-1.
- Software/Languages: Matlab, Python, JMP, C#, Java, C/C++, assembler (e.g. BF561), VHDL

## Key results

- Finalization of X-ray system and transfer to production including pFMEA of production process.
- Successful liaison between R&D and RA on technical documentation for conformity assessment of EU MDD Class IIb product.
- Designed and developed a manufacturing method for an advanced calibration object allowing co-calibration of optical systems with an X-ray system.
- Developed and realized concept for accurate color scanning in market leading intraoral scanner.
- Build ISO 13485:2016 and MDR compliant QMS in a start-up company.

## Personal Characteristics

Bo is curious in nature and thrive by digging into complex and multidisciplinary problems. He uses his broad and solid technical background to facilitate and engage in deep discussion and analysis to bring about the best solution or find the best way to attack a problem. He is great at leading task forces and always has an eye on the timeframe and on delivering results.

With more than 10 years of experience developing medical devices, he also understands the regulatory requirements, processes and documentation needs very well.

## References

**Medicologic (2020 - )**
Senior consultant
Medical Devices R&D Expert

**Undisclosed (a leading animal health company)**
Developing the next generation instruments for diagnostics of companion animals. Helped define key user needs and refine those to system, hardware and software requirements. Designed optical system as well as defined and developed control measures for ensuring quality and performance of final instruments.

**Radiometer**
Updating technical documentation in preparation for MDR re-certification audit including design control, verification and risk management.

**3Shape**

**Systems Engineer**
A leading force in building and finalizing the design and technical documentation for a new 3D X-ray (CBCT) scanner for conformity assessment by Notified Body (EU MDD Class IIb).

Design transfer to production, including risk management of production processes including verification of risk control measures and validation of outgoing QC processes.

**Project Manager**
Developed the technology allowing simultaneously acquisition of 3D geometry and accurate color texture scanning on 3Shape's intraoral scanner (EU MDD Class I).

Matured design and production of intraoral scanner to increase product quality and reduce manufacturing time (2nd generation).

**Danfysik**
Project manager for power supplies for particle accelerators and MRI scanners. Managing the projects through design, purchasing, production, testing and site acceptance testing.

**Snapform**

**Co-founder**
A med-tech startup developing better prosthesis for lower limb amputees.

Build ISO 13485 and MDR compliant QMS as well as defining the regulatory strategy for bring the product to market.

**Hasselblad**

**R&D Engineer**
Responsible for implementation of all image correction algorithms on Hasselblad's 40, 50 and 60MP camera backs.

Implementation in C and assembler on Blackfin BF561 DSP from Analog Devices.

**Patents**
Main inventor on 4 issued patents.

**Courses**
Design Control for Medical Devices (2 days) by Gantus
Data based decisions (1 days) by NNE
Statistical Design and Analysis of Experiments (5 ETCS) at DTU
Project Management Training – Module 2 (3 days) by Implement
Project Management Training – Module 1 (2 days) by Implement