

QA DEVELOPMENT ENGINEER SOFTWARE

*Sweden or home-
based in Europe*

✉ **KRISTINA@ELEMED.EU**

Calling all Quality experts with SaMD or embedded software (IEC 62304) experience! We have a fantastic chance to join a wonderful company in a newly created position focused on New Product Development and software quality projects. If this speaks to you, read on!

THE COMPANY

This company has been enhancing performance in healthcare across the world for over 150 years so has a huge amount of history behind it including being the first company to mass-produce dressings for wound care. Even though they have developed and manufactured many revolutionary devices, the innovation doesn't stop and is done in-house!

They are always looking for new ways to improve not just what they produce but also how they do business so have recently undergone a huge business transformation.



The value of work-life balance is strongly recognised here so this opportunity is open to be based from home anywhere in Europe. If you are looking for a large, established company that still feels like family, this is the place for you!

THE OPPORTUNITY

Thanks to a big push into developing innovative software to accompany their wound care portfolio, this new position in Quality was created and we are looking for you! This is an opportunity to work on high-priority software medical device development projects from a QA perspective. From design control to design transfer to the QMS, you will support the company to formulate processes and procedures further when it comes to software medical devices making a big change and big impact on the future of software within the business.

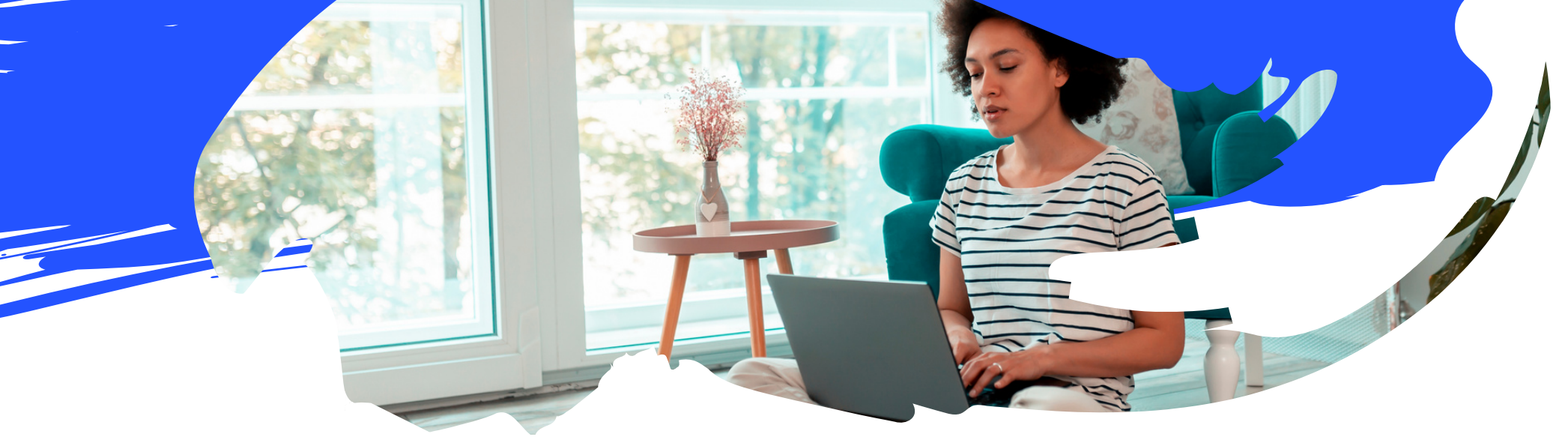
With the diversity and variety from project to project, you can guarantee that you will not get bored and be empowered to continually develop your professional skills. As well as software, you will also have the chance to work on the company's vast wound care portfolio thus not limiting your job scope. This friendly team enjoys having fun with work and is ready to welcome you in. If you're ready for a step into fresh shoes where you can mold and shape them to fit you, this is the position for you.



RESPONSIBILITIES

As QA Development Engineer Software you will (not an exhaustive list):

- Advise on change and design control activities, risk management, and other processes related to the QMS and ensure they are effectively followed during NPD projects and product changes for active and software medical devices
- Support the continuous improvement of the quality management system in line with relevant standards and regulations and ensure its implementation and maintenance
- Assess and review technical documentation relating to product development projects and ensure they meet the necessary relevant requirements
- Partake in external and internal audit activities
- Work in collaboration with other quality and R&D teams/departments/managers
- Address quality issues that could jeopardize the compliance to processes i.e. PMS, Risk Management, Design Control, Change Control etc
- Be the SME for software quality-related topics for other departments
- Support on other various projects relating to the business where necessary



YOUR QUALIFICATIONS

- 3+ years of quality assurance experience in the medical device industry with a focus
- SaMD or embedded software (IEC 62304) experience
- Willingness to travel occasionally to Sweden
- Eligibility to live and work in Europe

INTERESTED TO EXPLORE THIS FURTHER?

If you are interested in this exciting role, please send your application directly to [**kristina@elemed.eu**](mailto:kristina@elemed.eu)

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