



Email not displaying correctly?
[View it in your browser](#)

Contact us
+44 345 080 9000
medicaldevices@bsigroup.com



Regulatory review

Your monthly medical device update
January 2023

Featured in this Newsletter

- Introduction and welcome to Alex Laan - Head of IVD, Notified Body
- Clinical Masterclass Series Webinars 2023 - on demand - Preparing for a Clinical Evaluation Plan
- UKCA brochure now available
- Compliance Navigator - BS EN ISO 14971 and risk management - white paper
- Events for your calendar

Introduction and welcome to Alex Laan, Head of IVD, Notified Body

"By strengthening the BSI IVD Notified Body, I wish to continue with the quest to further support and improve the healthcare system in Europe"

Alex Laan Head of IVD Notified Body, BSI



Alex Laan recently joined BSI as the Head of IVD Notified Body. In this position, Alex will be focusing on further strengthening the regulatory foundations within the IVD team, whilst making BSI future-proof for the years to come.

Alex is originally a biochemical engineer and worked on the design and development of ELISA based assays in virology and immunohematology tests. He has worked as a technical specialist in reagents and

tests at Sanquin blood bank located in Amsterdam.

Over the years, Alex gradually moved into quality management and regulatory affairs, supporting a start-up company getting their CE-certification for a large IVD product portfolio.

After being active in industry, he worked at DEKRA for more than 12 years, eventually acting as the Principal Certification Manager – MD & IVD Devices at DEKRA Certification in the Netherlands. In this role he was directly responsible for all communications with regulatory agencies and ministry of health in the Netherlands and Great Britain. Alex has recently completed four years, working as a consultant at NAMSA.

He holds degrees in Biomedical Chemistry, Biotechnology and Business Administration.

We are delighted to add his experience to our team.

Visit our [IVDR dedicated webpage](#) to discover our IVDR resources to support you or to discuss your application with BSI!

Clinical Masterclass Series Webinars 2023 - On demand - Preparing a Clinical Evaluation Plan



Due to popular demand, our clinical masterclass series of webinars is here again for 2023 with new and exciting content for you.

These 5 webinars will help you focus on various aspects of the MDR, from preparing a Clinical Evaluation Plan, to supporting you with preparing a Clinical Evaluation Report, as part of an in -depth, 2-part webinar.

Additionally, we'll also provide guidance on preparing a Post Market Clinical Follow Up Plan and Evaluation Report (PMCF) as well as helping you to understand how best to produce a compliant Summary of Safety and Clinical Performance (SSCP) for both healthcare professionals and patients.

Listen back to our first webinar of the series: [Preparing a Clinical Evaluation Plan](#).

To find out more and to register for all 5 webinars, click on the button below.

[Register for the
Clinical Masterclass
Series](#)

UKCA brochure now available

Visit our [UKCA dedicated webpage](#) to discover our [new brochure](#) on UKCA marking with BSI!

This guide will take you through our certification process starting from your application to BSI to your UKCA Certificate issue.

Discover the process and the information needed to certify your device with BSI!

[Download UKCA
Brochure](#)



BS EN ISO 14971 and risk management | Medical devices white paper

International standard BS EN ISO 14971 was developed to provide a process to assist manufacturers in identifying the hazards associated with medical devices, assessing the corresponding risks, controlling these risks where needed, and monitoring the effectiveness of the risk control measures.

This white paper was first published in 2019 and has subsequently been updated in July 2022.

[Download whitepaper](#)

Events for your calendar

We have some fantastic events for 2023. Take a look now at our calendar of events for 2023.

Don't miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest [Events and Conferences](#).



bsi.



{{dynamic_content_4068}}

[Unsubscribe](#)

{{dynamic_content_3818}}

Inspiring trust for a more resilient world.