INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

Biel, 2 December 2020

Changes in Europe und UK

Dear customers and partners,

A crazy year is coming to an end. We all have had many new experiences, hopefully also some positive and instructive new discoveries that will have a lasting effect.

I would like to inform you about some exciting changes:

Security for Swiss manufacturers thanks to a streamlined solution for EU Authorised Representatives (EAR)
Swiss manufacturers are currently hanging in the balance. Without a Framework Agreement (InstA), there will be no MRA update and thus no equivalence between the medical device regulation in Switzerland and Europe from May 2021. It would be time for politicians to decide how to deal with this situation. Regardless of this, manufacturers will have to adapt - hopefully only for a limited time - to the situation where Switzerland is a third country. This means, among other things, in concrete terms:
– **Every manufacturer**, exporting to the EU needs an EAR for all products (MDD/MDR or IVDD/IVDR)
– This is connected with an adjustment of the labelling etc.
– The **SRN** (Single Registration Number), which is a prerequisite for applying for a conformity assessment procedure with a Notified Body under MDR/IVDR, cannot be obtained from Swissmedic. However, since 1.12.2020 manufacturers can apply for the SRN here (EUDAMED) if the authorised representative has been nominated beforehand.
– The authorised representative is jointly liable and will therefore carry out an in-depth document check.
– With a **Letter of Intent** with our EAR-partner you can ensure that you have an EAR on time.
On the subject of EAR, we have put together a service package, which we offer to a limited number of customers. It ensures that you can continue to operate in the EU market. You can find more details here.

Brexit and UK-Rep, actions already required by 1.1.2021
As of 1.1.2021, all manufacturers operating in the UK must have a UK-Rep notified. We can also offer a solution here. With a "Delegation Letter" from the UK-Rep, which can be issued after a preliminary examination of the technical documentation, you can be sure that you can continue to export seamlessly to the UK from 1.1.2021. The UK-Rep services are an extension of the above-mentioned EAR services. There are many synergies here, as the required documents etc. are very similar. We are happy to receive your enquiries here about pricing etc.

PMS Packages for MDR Compliance
One of the important innovations of MDR concerns the Post Market Surveillance (PMS). Many manufacturers are concerned about the increased requirements and associated tasks. In order to offer manufacturers the best possible relief and support, we have put together a series of packages to ensure MDR compliance. You define the level of support and we accompany you or take over the responsibility for your PMS. For customers who hand over larger parts of their PMS to us, we offer warranty services in case of audit non-conformities.

Start PMCF studies now
Clinical data are the gold of the next MedTech years, as they will be enormously helpful in re-registration under MDR. We help you to make this treasure available to you. Our experience clearly shows that with experience and creativity even relatively slim designs can be realised and often a great benefit for marketing is generated.

Firmware Development in conformity with IEC 62304
Only few people can develop software and firmware for compliant medical products. Thanks to our unique combination of technical and regulatory know-how, for years now we have been developing software and firmware for a wide range of our MedTech customers with great enthusiasm. Read more about this here.

Cyber Security
Cyber security is another important topic of the hour and also of the future. MedTech infrastructures have increasingly become the target of attacks, and the expectations of customers and regulatory authorities have risen accordingly, which is also reflected in an expansion of the corresponding standards (e.g. IEC 60601-4-5). We have built up a lot of know-how on this topic and have also developed an introductory webinar. Please contact Matthias.Steck@iss-ag.ch if interested.

Some ISS Internals news
- Annika Lörtscher is now responsible for the product management of our submission management tool REGULA™.
- As of December 1, 2020, we are strengthening both our knowledge management and our Global RA team with a total of five new employees.
- As of 1.3.2021, Christoph Anderegg will take over the SW development division. He replaces Andreas Müller, who will continue to support us as an independent software developer and architect.

I wish you a wonderful Advent season despite all the circumstances. The appeal to move in a small circle also includes the chance to find peace and to pause for a moment.

Sincerely,

Hansjörg Riedwyl
CEO