Secure your CE marking and access to Europe

– Partner with us for your EAR representation.

QAdvis EAR is based in Sweden, from where we provide a most efficient and effective and Brexit safe EU representation with full access to the European market

Our EAR consultants are accomplished European MDD and IVDD experts with many years of experience in the industry, including working as senior product documentation assessors at Notified Bodies. As your EAR, we are delighted to support you in the CE marking process of your products, according to the new European MDR and IVDR regulations.

We will be your contact with the various national Competent Authorities (CA) in Europe. As part of our services, we can help you through the different steps to CE marking, such as classification, identification of EU standards, technical file reviews, product notification and registration to CA, labelling reviews, and more.

We arrange the Certificate of Free Sale (FSC) on your request via the Swedish CA. Our team can provide unique regulatory support, for example concerning medical device software or clinical evaluation. You can ask us anything regarding this process; we are never more than an email or a phone call away.

QAdvis AB is based in Sweden with two offices – Lund and Stockholm. We are longtime trusted providers of expert MedTech quality and regulatory services, risk management incl. software RM, compliance, clinical evaluation, audits, training.

Members of European Association of Authorized Representatives (EAAR), and several ISO/IEC standard committees.

European Association of Authorised Representatives

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