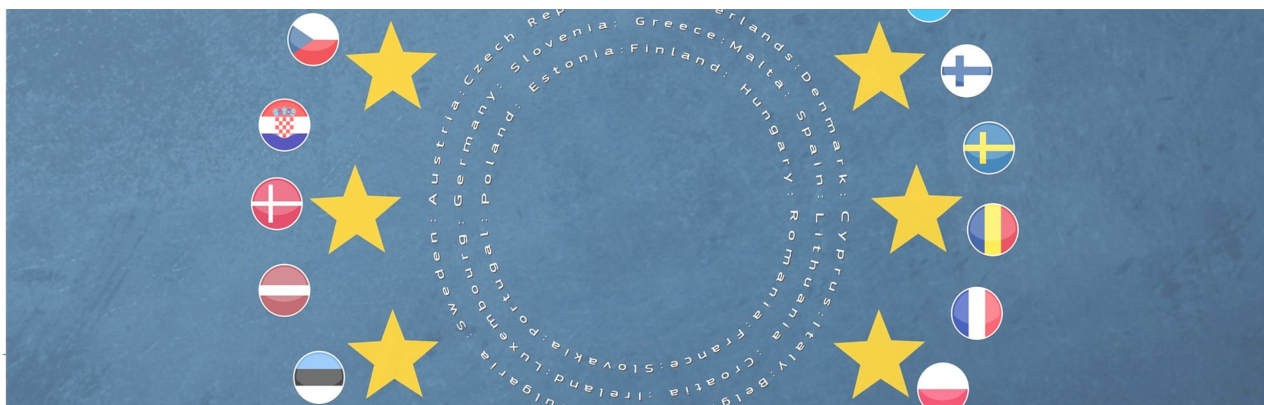




AR Authorised Representative in EU

SRN SE-AR-000001888

If you are a manufacturer located outside EU you need to appoint an authorised representative, AR. In all new EU regulations this is needed and the AR have extensive responsibilities for the products compared with how it used to be.

Benefit to appoint separate company

Instead of having e.g. the main importer or distributor to have this role in EU a separate AR enables you to change distributor in a much easier way without the need of changing labels and user manuals etc. This give increased flexibility.

Why use us?

We are a small dedicated team that cares about the manufacturers we represent. You will always have our full attention and we will support you all the way.



Our offering

We give a fixed prize that are tailored to your type of product(s). Always included are our representation, required yearly reviews and some hours consultations.

Vigilance and other authority handling are charged according to a separate pricelist if the need for this should arise.

Postal Address:
Högåsvägen 125
SE 741 41 Knivsta
Sweden

Hoff & Lowendahl

Phone: +46 (0) 722313355
E-mail: info@lowendahl.eu

Visiting Address:

Forsbyvägen 1B
SE-741 40 Knivsta

Hoff & Lowendahl

Place of business

Since our place of business is Sweden your authority in EU will be the Swedish authority (www.mpa.se). Technical documentation can be in English.

We are a member of Swedish Medtech (Medtech Europe associated) that organise the Medtech companies in Sweden which together with the Swedish authorities works to ensure safe and effective products.

We offer

- Help in development and verification of the technical documentation and quality systems
- Help in all regulatory matters, but also in interconnected sales e.g. participating in tender-meetings
- Manufacturer and product registrations
- Vigilance reporting support/handling
- We can also help to secure market access in other markets outside EU. Since we need access to the technical documentation this can easily be handled

Since our name will be on your label we will be into this together and hence a long term solution for your needs.

Postal Address:
Högåsvägen 125
SE 741 41 Knivsta
Sweden

Hoff & Lowendahl
Phone: +46 (0) 722313355
E-mail: info@owendahl.eu

Visiting Address:
Forsbyvägen 1B
SE-741 40 Knivsta