



**Your trusted partner and EU
Authorised Representative**

EC

REP

As your trusted partner and EU Authorised Representative Asphalion will guide you to comply with European regulations for Medical Devices and IVD:

- Contact point with EU Competent Authorities and Notified Bodies
- Support with Medical Device and IVDs registrations, as required
- Keeping Technical Documentation and Declaration of conformity available upon Health Authorities request
- Regulatory intelligence: stay always up to date on legislation changes and how they can affect your products

Why work with Asphalion?

- Expert MedTech professionals
- Good communication
- Similar business culture
- Strict confidentiality
- Full life cycle support
- Cost-effective solutions