When Medical Devices and IVDs meet REACh

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worldwide registration

The EU regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACh) affects also manufacturers of medical devices and IVDs. REACh requires producers of medical devices and their component suppliers, to examine their products and identify any 'substance of very high concern' (SVHC) based on environmental hazards (e.g. endocrine disrupting properties). **How does this affect your device registrations and approvals? Device exemptions in regards to REACh authorisation might not be applicable anymore.**

Our global experts are happy to assist you!

- Check whether your devices are affected
- Evaluation and analysis of alternatives early in the Research and Development process
- Monitoring of SVHCs according to your device portfolio and manufacturing procedures including frequent updates
- Regular updates and warnings for new SVHC substances and priority lists
- Screening assessment for indications of potential endocrine disrupting properties of substances
- Assessment and evaluation of environmental hazards as part of the authorisation process
- Services in regards to authorisation of substances, e.g. socio-economic analysis

IVDs: in vitro diagnostic medical devices

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