Your innovation experts in natural health products

# MEDICAL DEVICES

*Full compliance with new requirements*

The new Medical Device Regulation (MDR) means considerable changes for substance-based medical devices. Since May 2021, products such as nose sprays containing nothing but a saline solution are class IIa or higher. Previous class I devices need to be upgraded by May 2024 at the latest with the involvement of a Notified Body in order to keep their CE mark. The majority of in-vitro diagnostic products are facing similar challenges due to the new classification rules of the In-Vitro Diagnostic Regulation (IVDR). The IVDD-to-IVDR transition period will end in May 2022.

We support manufacturers of substance-based medical devices, combination products and in-vitro diagnostic (IVD) medical devices with tailored solutions to bring to and keep their products successfully on the market.

## OUR SERVICES INCLUDE

- Competent and flexible support at all stages of your product development
- Clarification of **demarcation issues** (medical device – food – drug)
- Assessment of your medical device risk classification according to MDR or IVDR
- Check of **regulatory requirements** for your medical device
- **Gap analysis** pre-market and throughout the product life cycle
- Consultation procedure for **medical devices with pharmacological substances**
- Correspondence with Notified Bodies
- **Coordination and conduction of studies**, e.g. biocompatibility testing, transportation evaluation, usability studies as well as clinical studies, e.g. observational study or randomized controlled placebo trial (RCT), to support performance and safety of your device
- Compilation of the **Technical Documentation**; including
  - Biological Safety Evaluation Report (BSER)
  - Substance-Based Device Information (SBDI, for substance-based MD)
  - Clinical Evaluation Plan and Report (CEP and CER)
  - Performance Evaluation Plan and Report (for IVD)
  - Post-Market Clinical Follow-up (PMCF) Plan and Report
  - Post-Market Performance Follow-up (PMPF) Plan and Report (for IVD)
  - Transportation Evaluation Report (TER)
  - Periodic Safety Update Report (PSUR)

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## TECHNICAL DOCUMENTATION

The technical documentation is required for all medical devices.
a&r experts will assist you in compiling your dossier in accordance with Annexes II and III of the MDR.

## CLINICAL EVALUATION

The clinical evaluation report provides a comprehensive assessment of all efficacy and safety data related to the product as well as to comparable and equivalent products. a&r will perform a thorough bibliographic evaluation on available performance and safety data to provide sufficient clinical evidence for your product. In case gaps are identified, a&r can support in generating clinical data with your product by coordinating and conducting e.g. in-vitro studies, observational studies, or even a randomized clinical trial in our own clinical study center.

## BIOCOMPATIBILITY REQUIREMENTS

The biocompatibility of the devices has to be stated in accordance with ISO 10993. a&r will determine the required tests, depending on the kind and duration of body contact. The required testing will be conducted by certified partner laboratories, and the results will be integrated into the biocompatibility evaluation of the technical documentation of the product.

## CONSULTATION PROCEDURES

If your medical device contains a pharmaceutically active compound, the Notified Body will consult a drug authority. A drug-specific documentation format (CTD) will then be necessary for your pharmaceutically active substance. Thanks to a&r's long-standing experience in drug regulatory affairs, our team can guide you through the consultation procedure, including the compilation of the necessary documentation as well as in negotiations with the drug authority.

# CONTACT US

**DR. HEIKE STIER**
Head of Consulting
and Strategic Innovation
*hstier@a-r.com*

**analyze & realize GmbH**
Weißenseer Weg 111
10369 Berlin – Germany
*www.a-r.com*