# Medical Device EU Registration – Routine Support

**Our service focuses on hands-on support throughout the registration process, including document creation, regulatory evaluation, document submission, and follow-up. With our expertise in regulatory affairs and quality management, we ensure efficient and compliant execution of activities to facilitate successful registration**

## Document Creation and Compilation

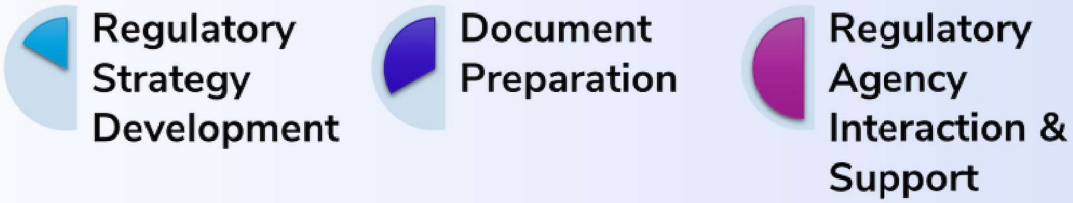
We work closely with clients to create and compile all necessary documentation required for EU registration, including technical files, design dossiers, and regulatory submissions.
Our team ensures that all documents are prepared according to EU regulatory requirements, including compliance with the Medical Device Regulation (MDR) and relevant guidelines.

## Regulatory Evaluation and Compliance Assessment

We conduct a comprehensive evaluation of documentation to ensure compliance with EU regulatory standards. Our experts review technical documentation, labeling, and quality management systems to assess conformity with regulatory requirements and identify areas for improvement.

## Submission Management and Follow-up

We manage the submission process and liaise with regulatory authorities on behalf of our clients to ensure timely and accurate submission of documents. Our team monitors the progress of submissions and provides ongoing follow-up to address any queries or requests for additional information from regulatory agencies.
We also assist in coordinating responses to regulatory feedback and facilitate communication between the client and regulatory authorities to expedite the registration process.

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- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific Provision of QMS

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