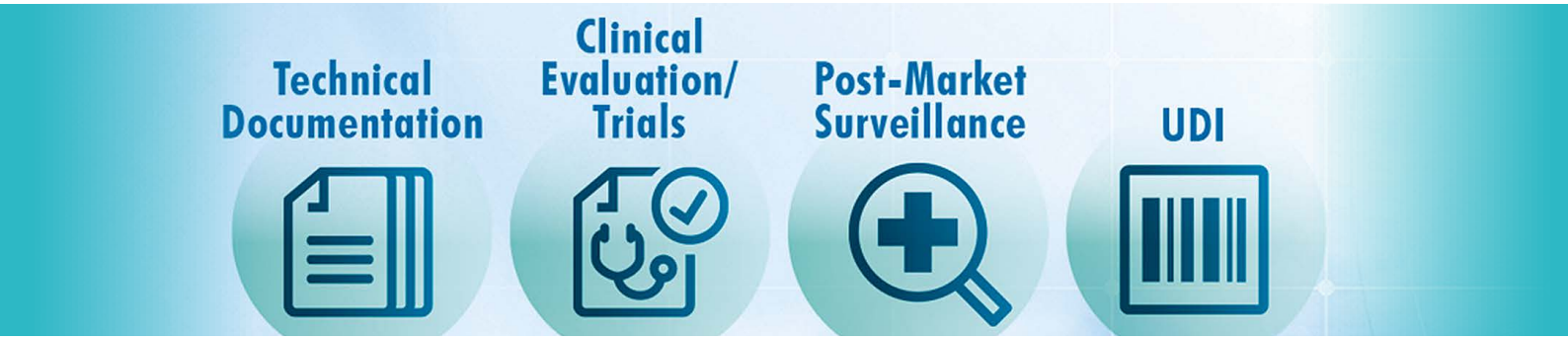

REFERENCE

MDR PRODUCT LICENSING

THE TASK

The new European Medical Devices Regulation (MDR) introduced considerable changes to approvel requirements for medical devices in Europe. EXCO is advising a medical device manufacturer on fundamental changes and requirements of the new regulation (EU) 2017/745 on medical devices and provides services for the legally compliant implementation of the new requirements for development, production and marketing processes.

EXCO SERVICES

- Consultation for MDR/IVDR requirements
- GAP analysis QM system
- Development and optimization of QM systems according to currently valid specifications
- Risk management 14971
- Employee training
- Compilation of product-specific standards and guidelines
- Creation of technical documentation
- Audit support

CLIENT BENEFITS

Harmonized QM system
The customer receives a QM system that is harmonized on the basis of DIN EN ISO 13485:2016 and the European Medical Devices Regulation (MDR).

MDR readiness
Our EXCO-MDR specialists are available at short notice, which provides our customer with a knowledge advantage so that their product meets all regulatory requirements.

Optimized risk management
As an experienced service provider for risk management according to ISO 14971:2019, EXCO provides its customers with support for risk management during the development and life cycle of a product.

Safe market launch
EXCO's knowledge guarantees the safe, efficient and timely marketing of the customer's product.

CLIENT:
Manufacturer of medical devices