ELLECOM®
Connected.Committed to Community

MARKET ACCESS FOR IN-VITRO DIAGNOSTICS AND MEDICAL DEVICES

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CRO SERVICES

- Clinical Strategy
- Study Start-up
- Monitoring
- Data Management
- Medical Writing
- Training
- Competent Authority Communication
- Ethical Committee Submission
- Institutional Review Board Procedures
- Pre-CE Study Design and Management

Regulatory Solutions for Manufacturers of Medical Devices and In Vitro Diagnostic

Performing a clinical study is a serious undertaking for every medical device and IVD manufacturer, requiring a strategic and practical approach.

ELLECOM's CRO team has accessibility to first-class facilities/equipment and dedicated experts to support advanced IVD and medical devices' expedited route to market.

This combination of different backgrounds, combined with ELLECOM's in-depth knowledge of regulatory affairs creates efficient and compliant clinical trials. Our expertise includes feasibility, pre-CE and post-market studies from class I to class III.

Because of our regulatory experience, we are able to provide our practical approach, leading to custom tailored trials. The advantage is that the design of the trial will be cost-effective.

Gap Analysis
Global Regulatory Strategy Advice
EU-MDR and CE Registration
EU-IVDR and CE Registration
EUDAMED
Risk Management - ISO 14971
USA FDA Market Access
China NMPA Market Access
ICMR Market Access
Local Representation
PRRC - Person Responsible for Regulatory Compliance
Interim Management
Regulatory Affairs Training
Global Registration

THE WAY TO / Switzerland

After Switzerland and the EU have not prolonged the Mutual Recognition Agreement (MRA) in 2021, Switzerland is effectively a third country. Placing medical devices on the market in Switzerland involves greater regulatory effort, but it is not impossible.

If the manufacturers' medical devices or In vitro diagnostic medical devices are on the market under the EU-MDR or EU-IVDR, then the manufacturer has already largely implemented the resulting requirements of the Swiss Medical Device Ordinance (MepV) or In Vitro Diagnostic Ordinance (IvDV).

The MepV now requires a completely new role: the Swiss Authorized Representative (CH-Rep). Ellecom offers Representative Services to manufacturers of medical devices and IVD devices.

Moreover, the Person Responsible for Regulatory Compliance (PRRC) is another mandatory role which is needed to comply with the regulatory requirements. Contact the Ellecom team to learn more about the provision of PRRC services.

Ellecom's customers will be notified of any changes to the European and the Swiss legislation, ensuring that their business will be minimally impacted.

ELLECOM® SWISS AG

SWISS
AUTHORIZED REPRESENTATIVE

ELLECOM SWISS AG :

Your Authorized Representative
in Switzerland

ELLECOM®

Your Authorized Representative
in European Union

The European Union requires any foreign manufacturer who intends to sell their devices in any of the Member States to designate a sole authorized representative (EC REP).

ELLECOM® GERMANY

European Authorized Representative

IND ELLECOM® (SGI) PRIVATE LIMITED

E–Labelling/e–IFU

Developed by the Regulatory Experts of ELLECOM ®

ELLECOM (SGI) Pvt. Ltd.

Your Authorized Representative in India

The ICMR (Indian Council of Medical Research) requires that any foreign manufacturer who does not have a legal entity in India needs to appoint an Indian Authorized Representative as soon as they initiate the product registration process.

Our Regulatory Experts specializing in MDs and IVDs are pioneers in offering electronic IFU (e-IFU) services. We have successfully tackled many of the challenges in implementation such as dealing with changes in regulations and perfecting the validation process to fulfil Notified Body expectations.

ELLECOM®

offers practical training

These training sessions are specifically designed for the Quality Assurance and Regulatory Affairs in the IVD and Medical Devices field.

ISO 9001:2015

ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

ISO 27001: Information Security, Cybersecurity and Data Protection – Information Security Management Systems – Requirements

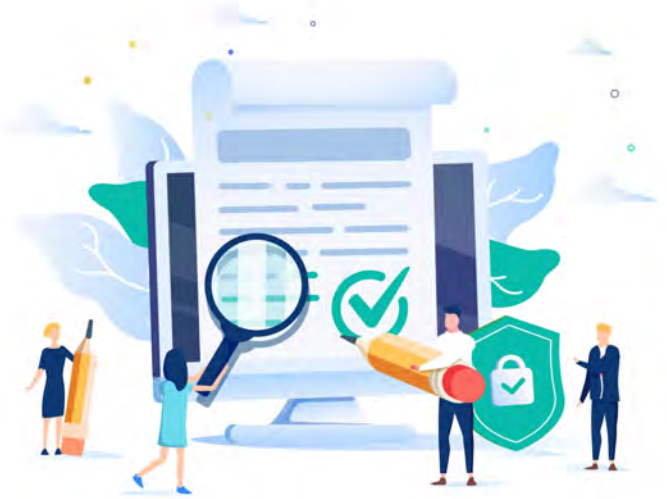
European Regulation 2017/746 on In Vitro Diagnostic Medical Devices

European Regulation 2017/745 on Medical Devices

INTERNAL AUDIT OF YOUR QMS

Audit is an opportunity to gain more insights into the company itself and the quality management system.

ELLECOM can perform first, second and third-party audit services for your company to make sure that your QMS conforms with the latest internal and external updates.



Beijing ELLECOM Technology Co., Ltd

CN ELLECOM®

Regulatory routes to enter the Chinese Market through NMPA Registration process

There's a difference between the regulatory route for foreign manufacturers and Chinese domestic manufacturers. In addition to the standard regulatory routes for Chinese market entry, there are several supplementary approval routes for faster approvals.

Our experts will assist you with up-to-date specialist knowledge, practical workshops and numerous applied exercises to comply with the NMPA regulations.

ELLECOM GmbH–ISO 9001:2015 certified

CERTIFICATE

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ISO 9001:2015

DEKRA Certification GmbH hereby certifies that the organization

Ellecom GmbH

Hauptstrasse 12, 79588 Efringen-Kirchen, Deutschland

for the scope of certification:

Sales & distribution of electronic components, medical devices and in-vitro diagnostic devices, as well as services to support and evaluate regulatory requirements for in-vitro diagnostics and medical devices

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. A20121218.

Certificate registration no.:	91021774
Validity of previous certificate:	-
Certificate valid from:	2021-10-20
Certificate valid to:	2024-10-19
Most recent update:	2023-07-06

Language translation

Dr. Rolf Krökel
DEKRA Certification GmbH, Stuttgart, 2023-07-06

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra.de/audits

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