Qualitas
International
Certification Ltd.UK

CE and EU Mark and Directives

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CE and EU Mark and Directives

Our Vision:
We aspire in association with our international alliances to become a premier key services & solutions provider to a wide range of industries in the region.

Our mission is to promptly provide our customers with superior quality and cost effective services and products, while maximizing the welfare of our stakeholders.

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General Objectives:
To become a recognized supplier for the Quality testing , inspection and Standard Certification industry.To support businesses with the latest Know How in the field of Environment Management System MIS Auditing .To expand our scope of supplies in the FDA/GMP & CE Marking sector.To continuously pursue profitable growth opportunities to our clients business throw QMS Auditing and certification .To provide the means to assist our customers in achieving their goals.To develop joint ventures with regional and international Training , Auditing and Certification industry leaders.To provide a rewarding and pleasant working environment for our international accreted auditors and team .

Compliance with the EU new approach directives

Qualitas international Certification Ltd. UK is you right service provider for your CE marked products advisory as well as many additional useful servises and information about the new approach EU directives.

With our regulatory and commercial advisory services, entering the European market with your CE marked products is no longer complicated or expensive.
We will, as a professional european advisor about Authorized Representative, clarify all the requirements and guide you through the EU regulatory "maze".
Without any fuss and long lead times, we make sure our clients take the quickest way through to the other side – the EU markets!

We guarantee!
Even as Qualitas International Certification is offering non-tangible irrevocable goods, we do issue a full guarantee if you are not fully satisfied.
100% Client Satisfaction is our aim!

For more information about the Service Guarantee, don't hesitate to contact us.

Medical Devices CE and EU directives

Are you having a hard time with the EU directives for medical devices, In-vitro diagnostic devices or Active implantable devices? Need a helping hand?

Qualitas International Certification is where you will find everything you need to know about our services for compliance with the EU directives for your medical devices, IVDs or AIMDs, as well as some additional useful information about the relevant directives.

Medical devices, IVD and AIMD products

Qualitas offers a whole range of services which can be ordered either as packages or as individual services.

We offer services where we acting as an Authorized Representative for your medical devices in the EU, as well as services where we only help you become compliant with the applicable EU directive, and let you, your distributor, or any other party to act as an EU Authorized Representative.

Our services include, labelling check, GMDN codes research and verification etc. Most of these services are also included in one or more of our service packages.

Our services

All you need to do is to choose an appropriate service below that suits your needs best, and contact us to provide you with an offer

1- AUTHORIZED REPRESENTATIVE SERVICE PACKAGES

1/1 - AUTHORIZED REPRESENTATIVE SERVICE (EC REP) FOR DEVICES THAT ARE NOT CE MARKED YET.
1/2 - AUTHORIZED REPRESENTATIVE SERVICE (EC REP) FOR CE CERTIFIED DEVICES.

2- INDIVIDUAL SERVICES

2/1 - MEDICAL DEVICE / IVD CLASSIFICATION
2/2 - CHOICE OF THE APPROPRIATE CONFORMITY ASSESSMENT ROUTE CONSULTING
2/3 - TECHNICAL FILE PREPARATION CONSULTING
2/4 - QUALITY MANAGEMENT SYSTEM IMPLEMENTATION CONSULTING (ISO 13485, ISO 9001)
2/5 - PROCESSES' RISK MANAGEMENT CONSULTING (ISO 14971)
2/6 - VIGILANCE SYSTEM IMPLEMENTATION CONSULTING
2/7 - ASSISTANCE IN OBTAINING THE CE CERTIFICATE
2/8 - GUIDANCE ON LABELLING REQUIREMENTS AND LABELLING REVIEW
2/9 - GMDN CODE RESEARCH AND VERIFICATION
2/10 - NON-EU REGULATORY SUPPORT
2/11 - TECHNICAL DATA SHEET TRANSLATION SERVICES

Our Scope of Experience

A- Popular Services

- Authorized Representative for medical devices
- Responsible Person for cosmetics
- GMDN codes for medical devices
- Free sales certificates for cosmetics
- Device classifications
- Assistance in obtaining the CE certificate
- Qualitiy management system implementation consulting (ISO 9001, ISO 13485)
- Preparation of Technical documentation for devices
- Preparation of Product Information File & Dossier
- Guidance on labelling requirements for medical devices
- Guidance on labelling requirements for cosmetics
- Notification of cosmetics
- Notification of medical devices
- Safety assessments for cosmetic products
- National Medical Device Registration

B- EU legislation

- Medical Device Directive 93/42/EEC - MDDIn
- Vitro Diagnostics Directive 98/79/EC - IVDD
- Active Implantable
- Medical Device Directive 90/385/EEC - AIMDD
- Cosmetics Regulation 1223/2009/EC
- Toy Safety Directive 2009/48/EC - TSD
- Machinery Safety Directive 98/73/EC - MSD
- Electromagnetic Compatibility Directive 2004/108/EC - EMC
- Low Voltage Directive 2006/95/EC - LVD
- Radio & Telecommunications Terminal Equipment Directive 1995/5/EC - R & TTE
- Pressure Equipment Directive 97/23/EC - PED
- Personal Protective Equipment Directive 89/686/EEC - PPE

Headquarter

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Certification & Training GULF/GCC

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Jumeirah Lake Towers JLT.
Silver Tower - ground floor
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Technical and Certification Advisory Management

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