NEXT

www.ceplus.eu

To request additional information, please see here.

MEDICAL DEVICES & IVD

REGULATORY AFFAIRS & MORE

Around the globe, **CE plus** assists companies both large and small to successfully bring their medical device and IVD products to market by providing expert regulatory services and strategies throughout the product life-cycle.

We help our clients maximize the value of their products by developing innovative and cost-effective solutions tailored to meet the needs and objectives of each and every client.

The product categories we support are:

- Medical devices
- Borderline products
- Combination products
- In vitro diagnostics
- Companion diagnostics
- Software / medical apps

CE plus provides you with:

- Pragmatic and custom-made solutions
- Consulting and/or full hands-on service
- Quick response time
- Working experience on both sides: industry and Notified Bodies
- Supported by an international network of experts: **regulanet®**

SERVICES

IT'S A JUNGLE OUT THERE

CE MARKING

The regulatory pathway to market success in the European Union can be quite challenging and requires tailored strategies adapted to the respective product.

Our vast experience in EU requirements as well as close contact with Notified Bodies and Competent Authorities allows us to effectively plan and implement the appropriate strategy for your product, saving you valuable time and expense while accelerating your time-to-market.

Our services include:

- Product classification and selection of a suitable conformity assessment procedure
- Compilation and maintenance of Technical Documentation
- Writing of preclinical/clinical evaluation reports and performance evaluation reports
- Development support (e.g. requirements engineering or usability)
- Verification of compliance with the Essential Requirements
- Selection of Notified Body/Competent Authority and relevant coordination activities
- Definition and admission of combination products
- Demarcation of borderline products and identification of the appropriate procedure for marketing authorization
- OEM / PLM support

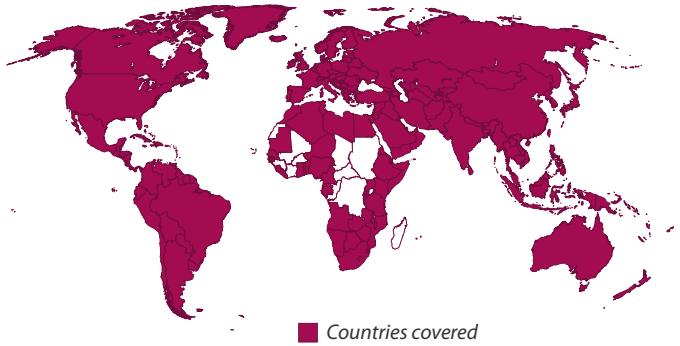
SERVICES

WE'VE GOT YOU COVERED

INTERNATIONAL REGISTRATION

As a global regulatory specialist, CE plus also provides medical device and IVD manufacturers with qualified distributors, local representatives, and authorization holders in over 90 countries around the globe.

Thanks to our worldwide network regulanet®, we can initiate your marketing authorizations in key markets outside Europe, such as USA, Canada and Australia as well as Brazil, Russia, India or China.



Ready to take your product to the global market?
Contact us today, we'll be more than happy to answer any questions you might have.

SERVICES

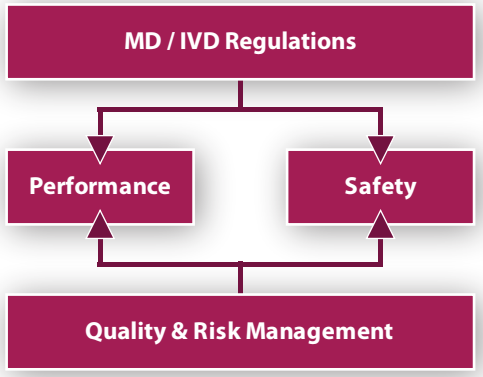
MINIMIZE RISK MAXIMIZE QUALITY

QUALITY & RISK MANAGEMENT

Our experts are there to assist you in setting up your quality and risk management systems in compliance with national and international requirements by offering:

- Support for the development, implementation and fostering of a customized quality and risk management system
- Compliance with QM prerequisites according to ISO 13485 and/or MDSAP
- Compliance with risk management related requirements according to ISO 14971
- Synopsis of different international requirements and integration into company internal QM system
- Establishment of a practicable documentation system

Requirements for Medical Devices / IVD



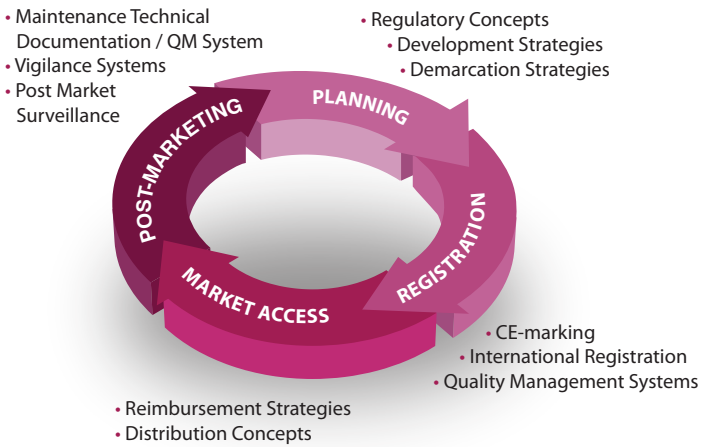
SERVICES

THE WHOLE PACKAGE

FULL SERVICE

Achieving a CE mark, gaining access to international markets or establishing a Quality Management System are great milestones. But there are many additional product life-cycle phases to cover with different needs. Whether it is a classical medical device or something unusual, we help you to progress and succeed by providing solutions for all product life-cycle phases.

See **www.ceplus.eu** for more details.



SERVICES

EXPERIENCE COUNTS

EXPERTISE

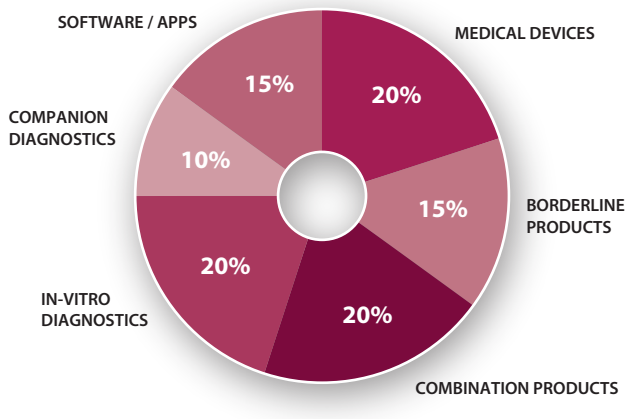
Our profound knowledge in regulatory affairs of medical devices and IVD is the capital we are working with. In summary, our knowledge reflects the expertise needed to support your project in an objective driven, pragmatic way:

- Regulatory affairs managers in medical device / IVD industry
- Notified Body auditors
- Skilled in communication with authorities
- Scientific background

We have successfully supported:

- A variety of over 200 clients from start-ups, mid-sized companies up to large international corporate groups
- A broad spectrum of medical fields and product categories

Our reliable expertise results in a high level of customer satisfaction: more than 50 % of our business is from new projects with repeat clients.



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Message:

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CONTACT US

HOW CAN WE SUPPORT YOU?

Call or contact us today, we'll be more than glad to answer any questions you might have and find the solution that fits your needs!

CE plus
MEDICAL DEVICES | IVD
Regulatory Affairs & More

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