

CE-PASS

CE Marking Support Service for Products for the EU Market

Machinery Directive

Low Voltage Directive

EMC Directive

Medical Device Regulation & IVD Regulation

Radio Equipment Directive

RoHS Directive

Pressure Equipment Directive





**We can provide you with total support
for complying with the CE marking for
products sold in the EU market.**

In order to distribute or use Japanese products in the EU market, the products must comply with the CE marking.

Before products are placed on the market, the CE marking requires that a conformity assessment is carried out according to the directives of the European Commission. Products that satisfy the directives, as well as the packaging, owner's manual, and other related materials, must display the CE marking.

Specifically, the manufacturer must select the directives and standards that apply to the product, create and translate the related conformity assessments, technical documents, owner's manuals, and service manuals, and build a system for monitoring the products after they are placed on the market.

CE-PASS is a complete service, encompassing all of these complicated processes and creation work, to help you ensure a smooth distribution of your products.



■ CE Marking Process

Step
1

Selection of Applicable Directives and Standards, Product Risk Analyses, and Conformity Assessments

- Selection of the applicable directives and standards, risk analyses of products, and creation of conformity assessments and test reports



Step
2

Creation of Various Technical Documents and Declarations of Conformity, and Display of the CE Marking

- Creation of technical files (design information, specifications, and so on), owner's manuals, and service manuals in English and other official EU languages
- Creation of declarations of conformity, and display of the CE marking



Step
3

Management by the Manufacturer, Importer, or Authorized Representative Located in the EU

- Storage and management of declarations of conformity, various technical files, and owner's manuals as the representative in charge in the EU

Distribution to the EU Market



Step
4

Market Monitoring of Products

- Manage all business matters with the competent authorities in EU countries as the manufacturer, importer, or authorized representative located in the EU
- Handle any problems that occur in the market. (However, the manufacturer is responsible for product-related problems.)

CE-PASS Services

CE-PASS is a representative support service for various requirements of the CE marking.



● Consulting Service for Declarations of Conformity

- Selection of the directives and standards that apply to products
- Risk analyses, as well as process confirmation and proposals for quality control and ensuring safety
- Support for verifying conformity assessments and creating test reports



● Service for Creating Technical Documents and Owner's Manuals

- Analysis combined with proposals for the structure and contents of technical documents according to the applicable standards
- Proposals regarding the contents and creation of owner's manuals and service manuals (analysis of compatibility with IEC82079-1)
- High-quality translations of created manuals and other documents into English and other languages



● Authorized Representative* Service

Note: The authorized representative is Crestec Europe B.V., our branch in the Netherlands.

Technical File Management Support

- Storage and management of technical documents, declarations of conformity and owner's manuals

Support after Products Are Placed on the Market

- Completion of procedures for registering products with the competent authorities
(For required products only. This support does not include export procedures.)
- Serve as the contact point with the competent authorities
Submission of declarations of conformity and owner's manuals
Submission of reports after products are placed on the market
Submission of market audit reports
- Handling of necessary matters if problems occur
The latest information regarding directives and standards can be provided in Japanese

*The authorized representative works on behalf of manufacturers located outside the EU. The representative in the EU serves as the contact point for the CE marking to comply with the market monitoring activities of the applicable competent authorities. Clients who do not have an office located in the EU can use our CE-PASS authorized representative service to respond quickly to inquiries from the competent authorities by concluding an authorized representative agreement with our European office.

Global Support

● Support Service for Directives and Standards around the World

In North America, Asia and other regions outside the EU, there are various systems associated with product directives and standards.


Like CE-PASS, we also provide comprehensive support for these systems.



● Product-Related Document Creation, Packaging Design, and Mass Production at Local Sites

In addition to our consulting service, we can create, translate, and print various documents, owner's manuals, and catalogs in high volumes, as well as design and mass-produce packaging, on a global scale.

With 20 branches located in 11 countries around the world (Europe, USA, East Asia, South-East Asia, South Asia) and 11 branches located in Japan, Crestec offers a complete lineup of services. From planning, writing, DTP and creation of various documents and owner's manuals to digital conversion of documents, multilingual translations, printing, binding, and design, mass production, and kitting of packaged products, we can deliver in all regions around the world.



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