Additional marks for medical devices with CE marking ?

- Other marks of quality, safety and efficacy mean additional tests (double or multiple inspections) and additional monitoring.
- Additional tests mean additional costs.
- Additional costs mean more expensive medical devices without increased benefit.

Conclusion:

Additional marks for quality, safety and efficacy of medical devices beside the CE marking may be confusing and are unnecessary because they cannot demonstrate more than the CE marking already does. They

- **do not** promote better health protection
- **do not** promote better performance,
- **do not** promote increased safety for patients, users and third parties.

Based on these facts, the CE marking legally affixed to medical devices is a factual mark of quality, safety and performance. Demonstrated evidence of safety and clinical or diagnostic performance of medical devices means quality. CE marked medical devices stand out from other products bearing a CE marking due to minor legal requirements.

Art. 17 Medical Device Directive (93/42/EEC):
"It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking."

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BAH

Bundesverband der Arzneimittel-Hersteller e.V., Bonn
www.bah-bonn.de

BPI

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www.vdgh.de

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Fachverband Elektromedizinische Technik im Zentralverband Elektrotechnik- und Elektronikindustrie e.V., Frankfurt
www.zvei.de/medtech

For further information please contact the associations listed above.
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The meaning of CE marking for medical devices

Important information for distributors, purchasers, operators, users and patients

What are medical devices?

A "medical device" is defined as any instrument, apparatus, appliance, material and software or other article intended for use for humans in the diagnosis, prevention, monitoring, treatment and alleviation of disease or as compensation for an injury or handicap.

The term applies to devices used for the examination, replacement or modification of the anatomy or a physiological process, for contraception, as well as for in-vitro diagnosis used in laboratories or by the patient for self testing.

All medical devices are subject to the laws and regulations transposing the European directives 90/385/EEC (active implants), 93/42/EEC (medical devices) and 98/79/EC (in-vitro-diagnostics) into national law. As a consequence medical devices must comply with essential requirements specified in the above directives.

Compliance with these comprehensive legal requirements ensures a high degree of

- health protection
- performance
- safety

- and that means quality - for patients, users and third parties.

What does the CE marking on a medical device mean?

By affixing the CE marking to a medical device a manufacturer documents that his product complies with the applicable essential requirements. Depending on the product's classification, a Notified Body is involved in the assessment procedure as an independent party and the CE logo must be accompanied by the Notified Body's identification number.

The CE marking ensures that the medical device has been manufactured in conformity with the applicable essential requirements specified in the directives and with national law. This procedure (referred to as the conformity assessment procedure) for **any** medical device, comprises:

Safety

- analysing, assessing and minimising risks and side effects
- ensuring biocompatibility, reducing and eliminating risk of infection
- ensuring electrical, electromagnetic and mechanical safety
- allowing or forbidding product combinations
- checking safety instructions and instructions for use for completeness and comprehensibility

Performance and benefit

- clinical or diagnostic evaluation of medical devices
- compliance with specified product properties
- ensuring therapeutic and diagnostic benefit
- ensuring measuring accuracy

Monitoring

- of the manufacturer
- of the medical device

during the entire life cycle of a product.

Who is responsible for ensuring that the CE marking lives up to its promise?

- **Manufacturer**

  The natural or legal person responsible for placing a product on the market, for fulfilling the relevant legal requirements, for tracking the product on the market and for notifying the competent authorities of the member states when incidents occur.

- **Notified Bodies**

  Independent auditing, certification and testing institutes for verification of product and quality systems as well as monitoring thereof.

- **Competent Authorities**

  The competent authority is the body which has the authority to act on behalf of the government of a member state to ensure that the requirements of the three European Medical Device Directives (90/385/EEC, 93/42/EEC and 98/79/EC) are carried out in that particular member state. Manufacturers or their authorised representatives are obliged to register with the competent authority in the country of their place of business and to specify the medical devices they are placing on the market. Among other things, the competent authority has to ensure that adverse incidents are reported within the appropriate timescales and are recorded and evaluated centrally.