3EC® international

CE marking

3EC International a.s. is a Notified Body (NB) EU with assigned identification number 2265 for the following EU directives:

- 93/42/EEC Medical devices
- 98/79/EC In vitro diagnostic medical devices

PURPOSE OF CE MARKING

(Communauté Européenne resp. Conformité Européenne)

By affixing the CE Mark on a product, the manufacturer assumes the responsibility that the product complies with all relevant and valid requirements of the EU harmonized legislative framework (New Legislative Framework NLF, or New Approach).

CE Marking is compulsory and inseparable marking of products to be introduced in the EU market, if not stated otherwise in the applicable directive. Without the CE Mark, products must not be introduced on the market or operate in the European Economic Area (EEA).

The main purpose of CE Marking is the harmonization of different national requirements of EU member states applicable to consumer and industrial products to support one common market and to increase product safety.

Rules and conditions for affixing CE Mark

- CE Marking must be affixed on the product or prduct label visibly, legibly and indelibly *(see Annex XII of Directive 93/42/EEC, resp. Annex X of Directive 98/79/EC)*
- If the nature of the product does not allow that, the CE Mark is affixed on the packaging and on the accompanying documentation, if such documentation is required by the relevant legislative framework
- The CE mark is followed by the Notified Body identification number, if the NB was involved in the manufacturing control
- CE Mark is affixed only by the manufacturer or his authorized representative
- CE Mark is affixed only on products for which the CE marking is governed by relevant EU legislative requirements

CE 2265

Manufacturer's responsibilities

- define the EU directives which must be applied for the relevant product
- to ensure compliance with all relevant EU directives
- to issue the conformity statement
- affix the CE Mark
- archive the technical documentation as the evidence of conformity assessment

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