Medical Devices Certificate And CE Mark Usage Procedure

5. Aim and Scope

The aim of this procedure is,

- To define responsibilities and conditions for clients for the usage of the certificates issued.
- To define responsibilities and conditions for clients for the usage of CE .... mark.
- To define rules for 'MCA' for auditing the clients for the usage of certificates and CE .... mark.

The rules for clients for the use of Notified Body Logo are not covered by this procedure. The rules for the usage of these Logos are defined in PR.10 Certificate and Brand Usage procedure under the scope of (EU) 2017/745 MDR and related legislation assessments.

'Malta Conformity Assessment Ltd.' will be referred as 'MCA' in this document.

6. Definitions

Refer to PR.MED.15 Procedure.

7. Responsibilities

All Personnel working in the Medical Device Department of MCA and MCA clients are responsible for the application of this procedure.

8. Method

8.1.Rules for CE ... Mark Usage

8.1.1. The number .... near the CE mark refers to the identification of MCA that is responsible for the conformity assessment procedures set out in Article 52 of (EU)2017/745.

8.1.2. CE .... mark can only be used for the products if there is a valid as per (EU) 2017/745.

8.1.3.CE .... mark can only be used on the product, on the product package, webpage and in the technical documentation related to the product.

8.1.4. When applicable CE .... mark should be labelled on the product itself.

8.1.5. In all cases, the instruction for use should contain the CE .... mark.

8.1.6. Rules for defining the usage of CE Mark in other regulations should be applicable also for the usage of CE .... mark.

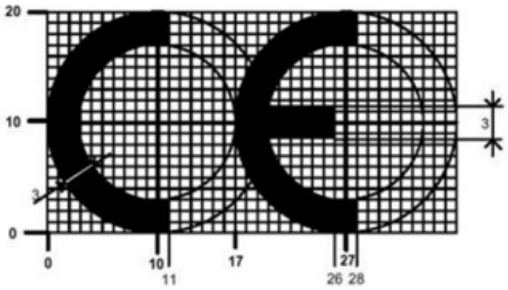
8.1.7. The number of .... should be placed right next to the CE Mark. When the..... number is used with CE Mark, the combined CE .... Mark should be readable.

8.1.8.CE Mark should have at least 5mm high. Each number of .... combined with the CE mark should also have at least 5mm high.

8.1.9. The aspect ratio should be kept when minifying and amplifying.

8.1.10.CE Mark should have below specifications.

8.1.11. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.



8.2. Rules For The Usage of (EU) 2017/745**Regulation Certificates**

8.2.1. The (EU) 2017/745certificates issued by MCA can only be used when they are current and valid.

8.2.2.CE .... Mark and certificates can not be used by the clients after the suspension date of the certificates.

8.2.3.CE .... Mark and certificates can not be used by the clients after the certificates are withdrawn. If there are already manufactured products with CE .... before withdrawal date and if the withdrawal reason is not related to product safety, the client may apply for being able to sell these products.

8.2.2. Certificates can only be used for the products and type/models which were defined in these certificates and in the related reports.

8.2.5. Certificate content can not be changed or edited by the client.

8.2.6. Older versions become invalid subsequent to the revision of the certificates. Clients can not use the older version of the certificates.

8.2.7. In case of a conflict between the printed paper version and the electronic version of the certificates, the electronic version stored in the MCA archive will prevail.

8.3.Audit Rules For The Usage of CE Mark and The Certificates
8.3.1. The audit team should control the usage of the CE .... mark and the certificates during the audits related to (EU) 2017/745Regulation and should report the results. FR.MED.85 Quality Management System Checklist shall be used for reporting.

8.3.2. During the audits, the following should be controlled;

- If the CE .... Mark is used only on the product, in the technical documents related to the product and on the product labelling or not,
- If the CE .... mark is not used for the products which are not in the scope of certification,
- If the CE .... mark was used on the product after the certification and before entering into the market or not,
- If the certificates were used only when they are valid.

8.3.3. During the audits, it should be reported if there is a case related to CE .... mark and certificate usage which is not in line with this procedure.

8.3.4. Rules for publishing EU Certificates and minimum content of EU Certificates are given as PR.MED.28 Procedure.

8.4. Rules In case of a Violation of Certificate and CE Mark Usage
8.4.1. If the audit team identifies a violation related to the certificate and CE Mark usage, the MCA certification committee is gathered urgently and this committee evaluates audit team data and suspends or withdrawn the certificate.

8.4.2. If the violation is the second violation of the company the certificates are withdrawn.

8.4.3. If the violation information comes through a complaint and if the is enough evidence related to the violation, the MCA certification committee may ask for an official explanation from the client. Complaints are handled according to PR.04 Assessment of Complaints and Appeals Procedure.

8.4.4. In case of a high level of suspicion but not proper evidence, MCA may perform an unannounced audit-related to the complaint. The result of this audit is submitted to the committee and the committee decides the next step.

8.4.5. After the withdrawal of certificates, if a violation related to CE Mark and certificate usage continues the files are submitted to the top management for initiating the legal process.