MEDICAL DEVICES CERTIFICATE AND CE MARK USAGE PROSEDURE

A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Zeynep Füsun Denli Tudan	31.01.2023

B) REVISION HISTORY

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4	The content is transferred to IQMemo	Transition to new software	31.01.2023

5.Aim and Scope

The aim of this procedure is,

- To define responsibilities and conditions for clients for the usage of the certificates issued by SZUTEST.
- To define responsibilities and conditions for clients for the usage of CE 2195 mark
- To define rules for SZUTESTfor auditing the clients for the usage of certificates and CE 2195 mark.
- The rules for clients for the use of Notified Body Logo is 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 Medical Devices Directive, 2007/47/EC, (EU) 920/2013 Regulation, (EU) 2017/745 Regulation*, Regulation no. 02.06.2021/31499*, other relevant legislation and auxiliary documents (NBOG, MEDDEV, GHTF, MDCG, IMDRF etc.

*The requirements to be realized in this document regarding the (EU) 2017/745 Regulation are only limited to specified for the transition period in Article 120.

6.Definitions

Refer to PR.MED.15.

7.Responsibilities

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

8.Method

8.1.Rules for CE 2195 Mark Usage
8.1.1. The number 2195 near CE mark refers to the identification of SZUTEST.

8.1.2.CE2195 mark can only be used for the products if there is a valid certificate according to 93/42/EEC Directive.

8.1.3.CE2195 mark can only be used on the product, on the product package and in the technical documentation related to product.

8.1.4. When applicable CE2195 mark should be labeled on the product itself.

8.1.5. In all cases the instruction for use should contain CE2195 mark.

8.1.6. Rules for defining the usage of CE Mark in other regulations should be applicable also for the usage of CE2195 mark.

8.1.7. The number 2195 should be placed right next to the CE Mark. When 2195 number is used with CE Mark, the combined CE2195 Mark should be readable.

8.1.8.CE Mark should have at least 5mm high. Each number of 2195 combined with CE mark should also have at least 5mm high.

8.1.9. Aspect ratio should be kept when minifying and amplifying.

8.1.10.CE Mark should have the below specifications.

8.2.Rules For The Usage of 93/42/EEC Certificates
8.2.1. The 93/42/EEC certificates issued by SZUTEST can only be used when they are current and valid.

8.2.2.CE2195 Mark and certificates can not be used by the clients after the suspension date of the certificates.

8.2.3.CE2195 Mark and certificates can not be used by the clients after the certificates are withdrawn. If there are already manufactured products with CE2195 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.

8.2.4. 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 revision of the certificates. Clients can not use the older version of the certificates.

8.2.7. Incase of a conflict between the printed paper version and electronic version of the certificates, the electronic version stored in SZUTEST achieve 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 CE2195 mark and the certificates during the audits related to 93/42/EEC 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 CE2195 Mark is used only on the product, in the technical documents related to the product and on the product labelling or not.
- If CE2195 mark is not used for the products which are not in the scope of certification.
- If the CE2195 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 CE2195 mark and certificate usage which is not inline with this procedure.

8.4.Rules Incase of a Violation of Certificate and CE Mark Usage
8.4.1. If audit team identifies a violation related with certificate and CE Mark usage, SZUTEST certification committee is gathered urgently and this committee evaluates audit team data and suspends or withdrawns 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 with the violation, SZUTEST 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, Szutest may perform unannounced audit related with the complaint. The result of this audit is submitted to the committee and committee decides the next step.

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