MEDICAL DEVICES CERTIFICATE AND CE MARK USAGE PROSEDURE

1. Revision History

Rev. No	Date of Rev.	Definition of Rev.	Reason of Rev.
2	1.7.2019	purpose section is revised	joint assesment 2019
1	7.6.2018	MDR Requirements are added	MDR transition
0	19.10.2015	First issue	System improvement for comission audit findings.

2. Related Standards, Guide Documents and Laws:

Code	Title
CoC 3.4	Team NB Code of Conduct for Notified Bodies Versiyon 3.4

3. Related Directives / Regulations

Code	Title
(EU) 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
93/42/EEC	Medical Device Directive

4. Related Internal Documents:

Code	Title
FR.MED.85	9342EEC and ISO 134852016 Quality Management System Checklist
PR.10	CERTIFICATE AND 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 2195 mark
- To define rules for Szutest for 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, Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013, Regulation (EU) No 920/2013 of 24 September 2013, 2017/745* * * /EU*, other relevant legislation and auxiliary documents (NBOG, MEDDEV, GHTF, IMDRF etc.

***Although the requirements for EU 2017/745 Regulation are defined in this document, all reuirements are out of scope and not applicable, until Szutest designated as a Notified Body by Designated Authority under the scope of EU 2017/745 Regulation.**

6.Definitions

See PR.MED.15

7.Responsibilities

All Personnel working in the Medical Device division of Szutest and Szutest clients are responsible for 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 as per 93/42/EEC and (EU) 2017/745.

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

8.1.4. When applicable CE2195 mark should be labelled 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.

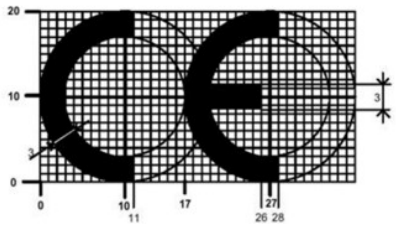
8.1.7. The number 2195 should be placed right next to the CE Mark. When 2195 number is used with CE Mark, the combine CE2195 Mark should be readable.

CE2195

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 below spesifications.



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 with 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 becomes invalid subsequent to revision of the certificates. Clients can not use the older version of the certificates.

8.2.7. Incase of an conflict between the printed paper version and electronic version of the certificates, the electronic version stored in Szutest archieve 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 with 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 reletad with 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 in to 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 with CE2195 mark and certificate usage which is not inline with this procedure.

8.4.Rules Incase of a Vaolation of Certificate and CE Mark Usage

8.4.1. If audit team identifies a violation related with certificate and CE Mark usage, Szutest certification commitee is gathered urgently and this commitee 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 throgh a complaint and if the is enough evidence related with the violation, Szutest certification commitee may ask an official explanation from the client. Complaints are handled according to PR.04 Assesment of Complaints and Appeals Procedure

8.4.4. Incase of a high level of suspision but not proper evidence, Szutest may perform unannounced audit related with the complaint. The result of this audit is submitted to the commitee and commitee 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.