MDR PRODUCT LOGO AND CERTIFICATE USAGE INSTRUCTION

1. PURPOSE

The purpose of this instruction is to explain the usage principles of UDEM Adriatic d.o.o. logos, mark and certificates accordance with the relevant product and apply to activities in case of misused of certified organization within the frame of product certification activities (conformity assessment activities under 2017/745/EU Medical Devices Regulation) implemented by UDEM Adriatic d.o.o. This instruction also determines the principles of usage and use of appropriate dimensions of product conformity marks (CE Marking).

In the preparation of this instruction, EN ISO/IEC 17021: 2015, EN ISO/IEC 17065: 2012 and EN ISO/IEC 17030:2021 standards, EA 2/17 M:2020 document, 765/2008/EC Regulation, 768/2008/EC Decision and 2017/745/EU Medical Devices Regulation were used as references.

2. RESPONSIBILITY

All persons and organizations that have been granted the right to use certificate, mark, logo and CE marking with notified body identification number "2696" as a result of the conformity assessment activities carried out by UDEM Adriatic d.o.o., as well as all personnel of UDEM Adriatic d.o.o. are responsible for acting in accordance with this instruction.

3. IMPLEMENTATION

3.1 Logo Usage:

UDEM Adriatic d.o.o. sends this instruction to clients together with a certificate,

After signing certification agreement, certified institutions by UDEM Adriatic d.o.o. are obliged to comply with provisions of this instruction as long as certificate validity continues. Also if certified institutions have certificate excepting product certificate (such as system certificate), they avoid using logo resulting ambiguity in usage of these certificates.

The client cannot use logo in scope and advertisements excepting certification scope. The client can only use logo in its scope and advertisements within certification scope. In the event of suspending or cancellation of certification agreement or related certificate, the client will stop using logo.

Clients may not use its product certification in such a manner as to bring the UDEM Adriatic d.o.o. into disrepute and may not make any statement regarding its product certification that the UDEM Adriatic d.o.o. may consider misleading or unauthorized.

In case of the restriction of the scope of certification by UDEM Adriatic d.o.o., all of the advertising/promotional/communication materials of relevant client shall be corrected according to the new certificate scope.

UDEM Adriatic d.o.o. continuously monitors whether the usage of certification logos, marks, certificates and CE marking by certified clients complies with this instruction and any related legislation/standard/guidance. Especially in the surveillance audits for certified clients, the usage of logo and certificate is assessed and reported by relevant auditors.

Processes of suspending or cancellation of certification are implemented to institutions neglecting specified requirements with this instruction.

UDEM Adriatic d.o.o. Certification Logo; Colour and shape changes cannot be made on UDEM Adriatic d.o.o. and Accreditation Logo. UDEM Adriatic d.o.o. Certification Logo is provided access from www.udemadriatic.com address.

The certificate is the property of the organization name on the certificate and in no way can be transferred to another organization or entity. The misuse of the certificate by third parties is the responsibility of the organization.

It can be confirmed that the certified organizations misuse the certificate or use the certificate information on presentation documents misleading the consumers.

This confirmation:

- Informing of UDEM Adriatic d.o.o. by other certified organization about the misuse of the certificate,
- Questioning the content of the certificate by contracting authority, consumer courts, private companies,
- Follow the visual and written media,
- It can be performed by observing during the realization of on-site audits (such as surveillance audits, unannounced audits, short-term audits etc.).

3.2 Usage of CE Marking:

'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in 2017/745/EU Medical Devices Regulation and other applicable Union harmonisation legislation providing for its affixing.

Medical devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of 2017/745/EU Medical Devices Regulation (MDR) shall bear the CE marking of conformity, as presented in Annex V of MDR and also in the Figure-1 of this instruction.

"CE" Marking;

1) According to the Figure -1 "CE" marking consists of "CE" letters and design cannot be changed without following the rate reduction and the expansion of the drawings.

2) The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale medical devices.

3) The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

4) The CE marking shall be affixed visibly, legibly and indelibly to the medical device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

5) The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

6) "CE" mark, is only placed by the manufacturer or his authorized representative.

7) Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52 of MDR. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

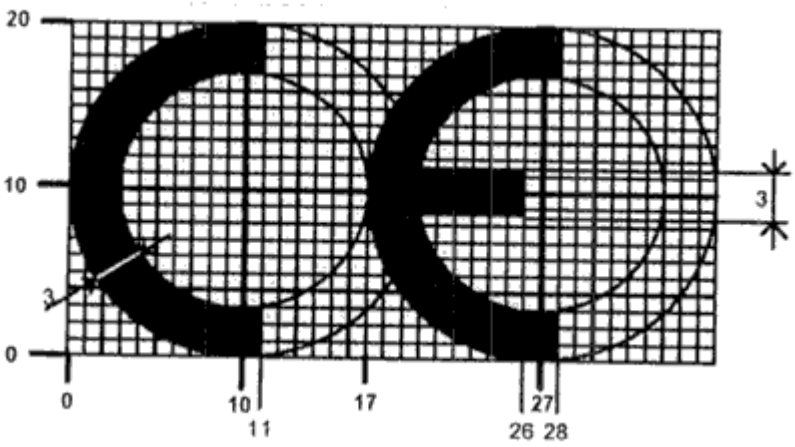
8) Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

9) On the product cannot be put descriptions or signs that may mislead the third parties about the meaning of CE Mark and shape. All kinds of other signs can only be put on the product that will not disfigure the visibility, the readability and the meaning of "CE" mark.

   Others point out all kinds of products but the "CE" marking the visibility can be without compromising the readability and meaning

10) "CE" marking is used on products that only foresees the imposition of technical regulations not used in other products.

Figure-1: CE Marking



3.3 Conditions under which corrective action is taken:

UDEM Adriatic d.o.o. requires a misuser to take corrective action whenever the mark of conformity has been affixed to a product that

- is hazardous, or
- is not authorized to bear the mark of conformity, e.g. because there is no record of the product in question having been certified; or does not comply with the applicable certification requirements to the extent that the integrity of the mark of conformity is jeopardized, or
- bears an unauthorized form of mark of conformity (e.g. counterfeit certification label), or
- is in violation of the certification agreement.

When either a report of misuse of a mark of conformity or of a hazard involved with a product bearing a mark of conformity is received by UDEM Adriatic d.o.o., the validity of the report is investigated.

3.4 Notifications:

Also in the case of a hazardous product bearing the mark of conformity, UDEM Adriatic d.o.o. informs the misuse of the need to take appropriate user notification action, advising of the hazard and the action to be taken.

The initial notification to the misuser; always is confirmed in writing by registered (or equivalent) letter with copies to the appropriate regulatory authorities and/or other bodies when relevant. (This letter is written to suit the particular circumstances, e.g. depending on whether or not it is practicable for the product in question to be recalled to the factory.) In either case it would normally contain;

- Reasons for corrective actions
- Any hazardous conditions that may exist
- The actions to be taken by the misuser to resolve the problem
- A statement covering the action to be taken to ensure that the mark of conformity is not applied to ineligible products.

3.5 Types of corrective action:

Where it is established that misuse has occurred, UDEM Adriatic d.o.o. determines the scope of misuse, including products, model number, serial/lot numbers, factory production facilities, production runs and quantities involved.

Corrective action could be one or more of the following:

a) Notification by UDEM Adriatic d.o.o. of parties authorized and responsible for instituting a recall when, in the opinion of the UDEM Adriatic d.o.o., such recall is necessary to protect the public, and to permit implementation of action;
b) Removing the mark of conformity from the product;
c) Rebuilding the product so that it complies with the governing certification requirements. (It is preferred that the rebuilding be done at the factory; however, when it is not practicable to recall some of the units in question to the factory, rebuilding may be authorized to be done in the field.);
d) Scrapping or suitably replacing a returned product because it is not practicable either to remove the mark of conformity or to rebuild the product so that it complies with the governing certification requirements;
e) Where a hazardous condition exists and it is not practical to implement a), b), c) or d), a notice to the general public about the hazard should be issued or action taken consistent with other national legislation.

3.6 In case of the mark of conformity under contract or using improperly:

When the corrective action has been resolved to the satisfaction of UDEM Adriatic d.o.o., the following should be undertaken:

a) All recipients of the letter which called for corrective action should be sent a second letter which states;
   - the suspension imposed upon the misuser has been lifted and that authorization to use the mark of conformity has been reinstated;
   - summarizes the corrective action taken by the misuser;
   - when applicable, describes the new marking required to distinguish the product in its corrected state from its previous unacceptable condition.
b) Certification records should be revised to include any modifications necessitated by the corrective action.

Where appropriate, Medical Devices Technical Regulation Responsible evaluates issues in cooperation with legal experts.

If the Medical Devices Technical Regulation Responsible confirms that the organization infringes the conditions of the contract and damages UDEM Adriatic d.o.o.'s reputation and does not take into account written warnings, the issue is submitted to the Certification Committee.

The decisions taken by certification committee are notified in written by Medical Devices Technical Regulation Responsible to the relevant organizations. According to the taken decisions, the lists on UDEM Adriatic d.o.o.'s website are updated and the public is informed.

3.7 In case of using improperly of the mark of conformity by non-parties under the contract:

Legal actions are initiated about relevant persons or entities and the decision on corrective action is left to the courts.

3.8 Degree of corrective action to be achieved

UDEM Adriatic d.o.o. considers that corrective action as appropriate has been carried out satisfactorily if:

a) the misuser has made a proper public announcement when asked to do so;
b) the products in the marketplace and distribution sites have been recalled, rebuilt, replaced or destroyed under supervision, or other corrections thereto made as required to the maximum degree feasible;
c) the misuser has agreed to continue the required corrective action on units which are in the possession of the user until the UDEM Adriatic d.o.o. is satisfied that the maximum practical result has been achieved, and
d) such necessary steps have been instituted in the manufacturing process to obviate the production of products which will again require similar corrective action.

3.9 Refusal to take corrective action:

When a misuser refuses to take corrective action, the following steps is taken by UDEM Adriatic d.o.o.:

a) cancellation of appropriate certification contracts with the misuser may be processed;
b) regulatory authorities involved and/or other bodies, when relevant, shall be informed that the misuser has refused to take corrective action and that certification contracts in the name of the misuser have been cancelled, where the severity of the case warranted such action;
c) legal counsel shall be obtained as to other action that may be taken (e.g. court injunctions, a press release by the certification body prosecution).

In the unlikely event that the POSHP (producer of a subsequently hazardous product) refused to take corrective action, notifying the public of the discovered hazard via the most appropriate news media.

3.10 Timing of corrective action:

When the facts are conclusive and corrective action is indicated but there is no misuser or POSHP to be held responsible (e.g. the company is bankrupt), or the product in question has not been produced for a number of years and is no longer available in the marketplace, UDEM Adriatic d.o.o. obtains advice from legal counsel and notify appropriate governmental, regulatory and public bodies.

3.11 UDEM Adriatic d.o.o. Product Certification Logo

UDEM Adriatic d.o.o. Certification Logo Terms of Use	
Usage Area	**Certification Logo**
On product	Utilizable
Advertisement : (e.g.: Large sizes ads, posters, tv ads, videos, brochures, web site)	It can be use with trade name and logo of the company
Promotional products	Non-utilizable
Flag	Utilizable

Vehicle	Non-utilizable
First packaging (on the package)	Utilizable
Second packaging (on the package)	It can be use on condition that an expression is to as follows: It was certified according to related Standard by UDEM Adriatic d.o.o.
Window sticky	Non-utilizable
Nonconformity report (Test/Calibration Report)	Non-utilizable
Laboratory tests , Calibration and reports of examinations)	Non-utilizable
Calendar/Agenda/Christmas Card	Non-utilizable

3.12 Usage of Identification Number of the Notified Body

The organizations which are certified according to following Regulation and Annex can use the CE marking accompanied by the number 2696 which is the identification number of the notified body of UDEM Adriatic d.o.o. and published in NANDO. Also the combined use of notified body identification number and CE marking is shown in Figure-2.

LEGISLATION	**MODUL/ANNEX**	**ON THE INSTRUCTIONS FOR USE AND PACKAGING**	**ON THE PRODUCT**
Medical Devices Regulation (EU) 2017/745	Annex IX Chapter I Annex IX Chapter II Annex XI Part A	YES	YES

Figure-2: Combined Use of Notified Body ID Number and CE Marking

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CE 2696	CE 2696

UDEM Adriatic d.o.o.'s notified Body ID Number (2696) cannot be used in any size or shape other than the dimensions specified in Figure-2.

When a use other than the one specified in Figure-2 is detected, the sanctions/measures in this instruction are applied.