POL07A NR CE marking

3EC International a.s. is an EU notified body with assigned identification number 2265 for the following EU legal acts:

- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
- Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices

Purpose of CE marking

CE marking means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing.

General principles of the CE marking

(art. 30 of the Regulation (EC) No. 765/2008)

1. The CE marking shall be affixed only by the manufacturer.

2. The CE marking shall be affixed only to products to which its affixing is provided for by specific Union harmonisation legislation, and shall not be affixed to any other product.

3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Union harmonisation legislation providing for its affixing.

4. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Union harmonisation legislation providing for its affixing.

5. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

6. In case of unauthorized use of the CE marking, the market surveillance authority imposes the fine from 200 EUR to 200 000 EUR to any person who affixes marking to the designated product, which may lead to the confusion regarding the CE marking or mislead the third parties. Criminal sanctions according to the § 170 to § 170b of Penal Code applies.

Rules for affixing CE marking on medical devices

(art. 20 of the Regulation (EU) No. 2017/745 / art. 18 of the Regulation (EU) No. 2017/746)

MD, other than custom-made or investigational MD, considered to be in conformity with the requirements of the MDR shall bear the CE marking of conformity, as presented in Annex V of the MDR. IVD MD, other than IVD MD for performance studies, considered to be in conformity with the requirements of the IVDR shall bear the CE marking of conformity, as presented in Annex V of the IVDR.

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

The CE marking shall be affixed visibly, legibly and indelibly to the MD / IVD MD or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the MD / IVD MD, 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.

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

Where applicable, the CE marking shall be followed by the identification number of the notified body no. 2265. The identification number shall also be indicated in any promotional material which mentions that a MD / IVD MD fulfils the requirements for CE marking.

Where MD / IVD MD are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the MD / IVD MD also fulfil the requirements of that other legislation.