POL07A NR CE marking

3EC International a. s. is 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 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 as amended (MDR)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU as amended (IVDR)

Definition 'CE marking'

(art. 2 point 43. of the MDR, art. 2 point 35 of the IVDR)

CE marking means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in above mentioned Regulations and other applicable European Union harmonisation legislation providing for its affixing.

General principles of the CE marking

(art. 30 of the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 as amended)

- The CE marking shall be affixed only by the manufacturer or his authorised representative.

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

- 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 European Union harmonisation legislation providing for its affixing.

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

- 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.

Under § 28 sec. 2 of the Act of the Slovak Republic No. 56/2018 Coll. on product conformity assessment, making the specified product available on the market and on change and amendment of certain Acts as amended the specified products surveillance authority shall impose a fine of between 200 euros and 200 000 euros on anyone who violates the provisions of this Act or provisions of the technical regulation in the field of conformity assessment (letter a)) by affixing mark on the specified product which may lead to confusion with mark (CE marking) or to misleading, (letter b)) by marking product that is not specified product according to § 4 sec. 1 of this Act with mark (CE marking) according to § 24 of this Act or by placing CE marking contrary to § 25 sec. 6 of this Act. Criminal liability for crimes defined in between § 170 and § 170b of the Act of the Slovak Republic No. 300/2005 Coll. Criminal Code as amended is also applicable.

Rules for affixing CE marking on devices

(art. 20 of the MDR, art. 18 of the IVDR)

Devices, other than custom-made or investigational devices, 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. Devices, other than devices 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 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.

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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.

Where applicable, the CE marking shall be followed by the identification number of the Notified Body No. 2265 responsible for the conformity assessment procedures set out in Art. 52 of the MDR or in Art. 48 of the IVDR. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

Where devices are subject to other European 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.