EC/EU type examination certificates and approval decisions for PPE in case of no deal Brexit

Date : 11/06/2019

To : EU Commission, DG GROW, unit C3 :
Barbara Bonvissuto, head of unit
Mario Gabrielli Cossellu, policy officer
Representatives of the member states in the PPE Working Group

The prospect of a no deal Brexit causes the PPE sector in the EU substantial concerns, partly caused by the fact that not all of the current UK Notified Bodies are ready with the anticipated alternatives.

Obviously, the first priority for PPE is providing the correct protection of the health and safety of the users, be it professional or private.

Based on documents issued by the EU Commission on the validity of type examination certificates and approval decisions issued by UK Notified Bodies, we have to conclude that those certificates and decisions become invalid in the EU27 immediately on the day of (no deal) Brexit.
On the other hand, the UK authorities have informed that there will be a transition period where CE marking on products will be accepted for a period (probably 18 to 24 months), this to avoid that products would not be available on the UK market and to give all stakeholders the chance to apply the new UKCA assessment and marking, in the event of a “no deal Brexit”

It seems that mainly the EU27 suppliers of PPE will have significant problems in this case. And this for several reasons :

- Out of the current 107 Notified Bodies for the Regulation 2016/425, 14 are based in the UK. This means over 13% of the total. Only 3 of those 14 have in the meantime a branch that is active and notified in one of the EU27 countries and are this way in a position to offer a solution (transfer of certificates) for their customers. The share of the UK Notified Bodies varies depending on the type of PPE, for instance for hearing protection, 8 out of 21 are in the UK.
- We estimate that the market share of the UK Notified Bodies with manufacturers that are based outside the EU is more significant than the 13% of Notified Bodies in the UK. This due to historical and language reasons.
- Most UK Notified Bodies have reassured their customers that they were working on a solution and that the manufacturer had ‘nothing to worry about’. In practice, in most cases, the conclusion today is that the announced solutions are not ready, and this for different reasons.

European Safety Federation ivzw | Bavikhoofsestraat 190 | 8531 Harelbeke (Belgium)
info@eu-esf.org | www.eu-esf.org | T+32 56 70 11 03
EU Transparency Register number : 91447653655-65

- Most Notified Bodies in the EU27 have already substantially longer lead times due to capacity issues as a result of the transition from the Directive 89/686 to the Regulation 2016/425. This means that they are not able/willing on short term to accept the transfer from UK Notified Bodies or to perform conformity assessment for new customers.
- Particularly SMEs are often less well informed, due to trusting on their suppliers (including Notified Bodies) for information and/or a lack of internal expertise and resources. And despite the efforts of the EU Commission, Member States and trade associations to spread as much information as possible.
- Even with a transfer of type examination certificates and approval decisions to an EU27 Notified Body, the manufacturer still needs time and resources to adapt all documents (instructions and Declaration of Conformity) and markings (in case of category III PPE) for the next production.

In practice this means that EU27 suppliers will be faced with problems when placing PPE on the market after a no deal Brexit. Not only manufacturers based in the EU27, but also distributors (that may now become importers) of products certified by one of the current UK Notified Bodies.

If the market surveillance (and customs) authorities apply the consequences of a no deal Brexit from the start very strictly, this will lead to problems for EU suppliers and may lead to supply issues on the EU27 market. And this might lead to unsafe situations for EU27 citizens.

We are convinced that nobody in the EU27 (nor in the UK) aims to jeopardise the health and safety of the citizens, nor the economic position of EU companies.

Therefore, in the case of a no deal Brexit, we ask for a flexible pragmatic approach concerning the type examination certificates and approval decisions issued before the Brexit date by UK Notified Bodies for a period similar to the transition period the UK will practice for CE marked products (18 to 24 months). This will allow all EU27 PPE suppliers to make sure that the certificates and approval decisions for safe PPE are transmitted to one of the EU27 Notified Bodies while assuring continuity on the market.

Henk Vanhoutte
Secretary General
On behalf of the ESF members

European Safety Federation ivzw | Bavikhoofsestraat 190 | 8531 Harelbeke (Belgium)
info@eu-esf.org | www.eu-esf.org | T+32 56 70 11 03
EU Transparency Register number : 91447653655-65