Brussels, 29th April 2009

Subject: Directive 2007/47/EC implementation

Dear Sirs,

We are aware that the European Commission is investigating whether there is a legal requirement to reissue all certificates as from 21 March 2010 or not. If a reissue is necessary, a high administrative burden is imposed on manufacturers and Notified Bodies. We are aware that most of the Member States have declared to be in favour of a legal interpretation that does not require reissuing all certificates, except if there is a significant amendment to the conformity requirements hereafter named "substantial amendment".

The Notified Bodies have analysed the situation that would arise if only a small number of the certificates were to be reissued. They are afraid that the addition "Directive 93/42/EEC as amended by Directive 2007/47/EC" would, in a first step, lead to an uneven "playing-field" for public tenders and markets outside the EU which, in a second step, would force manufacturers to require the same reference to be added to all existing certificates. At the end of the day, this would lead nearly all certificates being re-issued. In view of that fear, the Notified Bodies have tried to develop a technical solution that allows Member States to identify whether a certificate relates to the modified requirements of Directive 2007/47/EC or not. This technical solution would only be applied to those devices where there is a substantial amendment introduced by Directive 2007/47/EC so that re-certification is necessary. If not subject to a substantial amendment the existing certificates will remain valid or be renewed according to existing rules. After 20 March 2010, the technical solution would not need to be applied anymore – the existing rules will be applicable again.

a) If, between now and 20 March 2010, a certificate is to be issued (for the first time or as renewal) the certificate would be split into two, one being valid until the 20 March 2010 and the second having a date of validity from 21 March 2010 for the remaining time of normal validity (3 or 5 years). The second certificate would express to market surveillance authorities that the device has been regarded as being subject to substantial amendment by the directive (as hopefully soon defined by the authorities). The first certificate would indicate compliance with the existing directives.

b) In the case that the existing certificate has a validity going beyond 20 March 2010 whilst being subject to a substantial amendment by Directive 2007/47, the NB would have to withdraw the existing certificate on the 20 March 2010 and issue a new one (e.g. for the remaining period of the withdrawn certificate).

c) In both cases a) and b), no explicit reference to Directive 2007/47/EC would be needed.

We would like to recommend Notified Bodies, Member States and other interested stakeholders to accept this technical solution, which, alone, can assure a level-playing-field whilst guaranteeing transparency for market surveillance authorities.

Yours sincerely,

NB-MED

Contact: *Gert Bos , Chairman NB-MED, gert.bos@kema.com*
Michel Binard, Vice-chairman NB-MED, Chairman NBRG, michel.binard@snch.lu