Dear Notifying Authorities, dear Chairs of Notified Bodies Groups, dear colleagues,

In the context of the current COVID-19 outbreak, we understand that the activities of notified bodies may be affected, in particular insofar as this requires performing visits to manufacturers premises. Due to the exceptional circumstances we are facing, some of you have been asking us whether we should provide for flexibility and specific guidance on this issue.

We believe that notified bodies should continue to carry out their tasks to the extent that this is currently possible in view of the confinement measures taken at Member States level. Notified bodies are encouraged to perform remote assessment techniques, including document reviews, as far as possible to substitute or complement on-site assessments. However, remote or virtual assessments will not always provide a substitute to on-site visits which are required by notified bodies under specific modules. When faced with such situations, Notified Bodies are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardize the technical validity of that specific activity. Notified Bodies should also act with full transparency, informing affected clients of any change in the procedures and keeping records justifying the decisions taken.

These arrangements should however not put at risk the health and safety of products in the EU and the role that Notified Bodies play in conformity assessment. Notified Bodies are requested to inform the relevant authorities of any relevant issues relating to possible non-conformity of products, including where this may be relevant due to the need to postpone specific on-site visits in the context of the conformity assessment activities.

For information, please find attached the communication that EA has distributed to its members on this same issue.

Kind regards,

European Commission
DG for Internal Market, Industry, Entrepreneurship and SMEs
Unit B1 Free movement of goods

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