

Mrs. Hanane Taidi
Director General
TIC Council
Rue du Commerce 20-22
B-1000 Brussels
Belgium

Ms. Sandra Gallina
Director General
DG SANTE

17 February 2021

Subject: TIC Council Statement on the “Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies’ audits performed in the context of quality management system assessment”.

Dear Ms. Gallina,

TIC Council welcomes the European Commission’s Notice and appreciates the recognition that extraordinary measures, such as remote audits, are needed considering the exceptional circumstances caused by the COVID-19 crisis.

Nonetheless, TIC Council would like to see a more ambitious approach to achieve the Notice’s goals of ensuring continuous availability of safe and performant medical devices/IVDs and preventing shortages.

In TIC Council’s view, the Notice is very general and is mostly a cumulative set of circumstances and conditions Member States should take into account, when considering not to apply penalties to notified bodies for taking certification decisions under the MDR and IVDR based on remote audits only.

TIC Council thinks that to achieve the Notice’s goal effectively, a certain level of alignment across Member States, and consequently across notified bodies, is necessary.

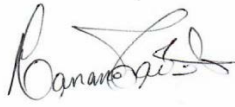
TIC Council calls upon the Commission and Member States to engage in a conversation, in the relevant expert groups and in cooperation notified bodies, **to identify elements of an aligned and risk-based approach on how the cumulative set of circumstances and conditions, as set out in the Notice, could be efficiently met under the circumstances dictated by the COVID-19 global pandemic.**

As transfer of devices from the Directives to the Regulations requires considerable time and effort from manufacturers as well as from notified bodies, and dates of application for MDR and IVDR, rapidly approaching, **TIC Council encourages the European Commission and Member States to foster this alignment effort without any delay and to involve the notified bodies from the start in order to ensure a speedy process.** Ideally, an aligned position could result in an (amended) MDCG, NBO or CAMD guidance paper. However, given current time and resource constraints across the MedTech sector, this might not be a realistic scenario.

TIC Council **would like to call for quick way to communicate the aligned position to the relevant stakeholders**, including notified bodies and MedTech industry.

The TIC sector welcomes the opportunity for further discussions with the Commission in support of an aligned and coordinated effort during these challenging times to ensure the continued delivery of life-saving medical devices in the European market.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Hanane Taidi', with a stylized flourish at the end.

Hanane Taidi

TIC Council

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