MedTech Europe Survey on MDR implementation

Background and More information

April 2022

Since 26 May 2021, the Medical Devices Regulation (MDR) has come into full application. An overwhelming majority of MedTech Europe members are reporting challenges with the MDR implementation.

Within the framework of our new MDR advocacy efforts, MedTech Europe and its members have identified priority areas that lead to an unpredictable and innovation unfriendly European regulatory system, e.g., challenges when transitioning Directive certificates, lack of notified body capacity, fragmented MDR implementation across Europe, implementation of guidelines, innovation, etc. We now need concrete evidence and data to illustrate these points and with that in mind, we are reaching out to you with a request to fill in a survey by 25 April 2022 (EOB).

Your feedback is of utmost importance to provide regulators with a realistic picture of the state of the MDR implementation - MedTech Europe therefore strongly encourages all members to reply to our survey.

The survey, which was drafted with the help of members, include core questions directly addressing questions from Authorities, i.e., the Medical Device Coordination Group (MDCG) Task Force on certification capacity monitoring, but also additional questions drafted by MedTech Europe.

If we do not receive compelling data, it will seriously threaten our chances of securing a positive MDR advocacy outcome for members and patients in the final 2 years remaining until May 2024. Furthermore, we would like to stress that if we cannot provide compelling data at industry level, we face the following risks:

1) Inability to secure EU-wide solutions to the MDR transition situation,
2) Loss of credibility as an industry in the eyes of the Authorities,
3) Continued fragmented national measures that create further challenges for our industry

We trust this message underlines the seriousness of the situation, and we count on you all to help us advocate on the present situation, by equipping us with usable data.

If you have questions on the confidentiality of the information you are going to provide you should know:

- Information will be aggregated
- Aggregated information will be used with EU institutions (Commission, Council and EU Parliament) and outside stakeholders
- Examples will be anonymized without reference to companies
- If you have questions, you can reach out to MedTech Europe's Legal & Compliance Senior Manager – Mr. Pablo Rojas

We need your help and thank you for all the time and efforts you'll dedicate to this important exercise.