

COCIR Recommendation

Need for remote audits under the MDR in times of COVID-19

Background information

The Medical Device Regulation (MDR) enters into force on 26 May 2021. To place a new device or a device that has undergone a significant change on the European market after that date, MDR certification must be in place – requiring an audit by a Notified Body. Annex IX 3.3 of the Regulation stipulates that “audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors”.

Problem statement

The current COVID-19 pandemic causes travel and other restrictions leading to delays of initial MDR certification audits, as Notified Body auditors do not have access to the physical premises of the manufacturer. Many audits have been postponed until the end of 2020 or even 2021. Some companies are even still waiting for the exact audit date from their Notified Body. **There is thus a high likelihood that not all COCIR member companies will have achieved MDR certification by the end of May 2021, even though they are ready and have prepared everything for MDR compliance.**

Some Notified Bodies have already announced that changes to devices certified under the Medical Device Directives (MDD) are not possible anymore after November 2020. In addition, when production has been planned according to EU MDR, there are often limited possibilities to step back to MDD production (due to supplier capacity, parts availability, documentation to be reworked, etc.).

In conclusion, if the current situation continues, we expect delays in product launches (or even shortages) for certain imaging, electromedical, radiotherapy and software devices next year. This is especially concerning as the pandemic situation is worsening and it is not clear if all re-scheduled audits will actually take place as planned. **If no solution is found, we see a direct threat to the availability of innovative medical devices to European healthcare systems and to the competitiveness of the medical device industry in Europe.**

Recommendation

In these extraordinary circumstances, urgent action is needed to allow **conducting initial MDR certification audits remotely** by using the latest Information and Communication Technologies¹. **COCIR calls on the Medical Device Coordination Group (MDCG) to expand the current guidance² on remote audits to all (not only essential for COVID-19) devices under MDR.** A condition may be introduced that the on-site audit must take place at the next surveillance audit.

¹ See also March 2020 guidance issued by the International Accreditation Forum (IAF) that proposes alternative auditing methods in extraordinary circumstances. The IAF also published a [statement](#) with specific guidance for COVID-19.

² April 2020 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_4_nb_audits_covid-19_en.pdf