COCIR Concerns

Impact of COVID-19 on certification and availability of medical devices in Europe

Since the start of the spread of COVID-19, our members' products have been in heavy demand in China and, increasingly, in Europe including Italy lately. Respiratory assistance devices (ventilators), patient monitoring systems, portable X-ray, ultrasound equipment and Computed tomography (CT) have been utilized in the response. In addition, our global companies shifted the supply priorities to meet the increased demand in affected countries and regions.

Due to the rapid increase in demand of the above-mentioned equipment, we would also like to highlight supply chain challenges while the COVID-19 outbreak develops and expands. The production of our equipment heavily relies on the functioning of global supply chains. It is therefore important to keep the production facilities of such products, accessories and components open in order to respond to the global demand.

These concerns are exacerbated by the uncertainty already surrounding the MDR implementation. The challenges and our recommendations around MDR certification and shortages of Class I Devices are outlined below.

Delays in MDR certification

Challenge

Travel restrictions and quarantine requirements for EU citizens in many countries mean that Notified Body auditors cannot access manufacturing sites. In addition, some Notified Body employees are quarantined or must follow travel restrictions in the country they are based in.
These restrictions have already led to cancellations or delays of audits and therefore delays in MDR certification or MDD certification renewals. Combined with the general challenges of available Notified Body resources, there will be product shortages for Europe, the impossibility to make significant improvements to existing devices, or place new models on the European market.

Recommendations

COCIR and its members urgently request the European Commission and Competent Authorities to allow Notified Bodies to exceptionally adapt their auditing practices for MDD EC certificate renewals as well as for MDR initial certification audits.

The following are some constructive adaptations that should be considered:

- **To replace** on-site audits by remote audits using Information and Communication Technologies (tele – and video conferences) when appropriate; or
- **To follow** international guidance[1] 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].
- **To use** existing recent MDSAP audit results in lieu of MDD/MDR audits where available; or
- as a last resort, **to allow** manufacturers to continue certifying products under existing MDD certificates while the impact of measures due to COVID-19 prevents certification under MDR.

---

1 IAF ID 3:2011 (IAF Informative Document For Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations)
IAF MD4 (Mandatory Documents for the use of ICT for Auditing/Assessment purpose) and ID12 (Principles on Remote Assessment)
2 https://www.iaf.nu/articles/IAF_Statement_on_COVID19/636

Shortages of class I Devices

Challenge

The use of many devices and systems in the COCIR manufacturers' product portfolio requires class I consumables and accessories. Examples of these devices include ECG electrodes, imaging media or disposable temperature probes (see non-exhaustive list below). Many of these devices are not manufactured directly by the COCIR membership but by other manufacturers and suppliers.
Class I Devices cannot benefit from the so-called 'grace period' under the Medical Device Regulation. They are not addressed by the second MDR corrigendum (that only includes MDD class I Devices that are up-classified under the MDR). These devices are required to be compliant from May 26, 2020 onwards.
Initially, the so-called 'warehouse clause' (MDR Article 120.4) was planned to be used by distributors to bridge the transition period. However, due to COVID-19, consumption of these Class I Devices (especially consumables) has increased exponentially. As production cannot keep up with demand, any available devices within Europe will be depleted far earlier than predicted. We thus expect product shortages for these devices after May 2020. These shortages would limit the use of devices and critical procedures required to diagnose and treat patients in Europe.

Recommendation

COCIR and its members recommend allowing MDD-compliant class I devices to be placed on the market after May 26, 2020. This could be implemented through a European derogation based on MDR Article 59(3).

Class I Devices potentially impacted by shortages due to COVID-19

This is a non-exhaustive list that will be constantly updated:

- Imaging Media for X-Ray
- Ultrasonic Gel
- Ultrasound Probe Covers
- Blood Pressure Cuffs
- ECG electrodes
- Disposable Temperature Probes
- Temperature Probe Patches – For Reusable Temp Probes
- Maternal/Fetal Belts
- Charting Paper
- ECG Lead wires
- Cables (trunk cables, temp cables, cardiac output cables, invasive pressure cables, etc.) and other connecting accessories
- Various sensors (pO2, temperature, air flow sensor, movement & position sensor, etc.)
- Positioning accessories
- Respiratory device accessories (cannulas, tubing, masks, etc.)
- Batteries
- Printing accessories