Mecomed Medical Technology Association
Middle East & Africa

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To:
Regional Health Authorities in Middle East and Africa

From:
Mecomed Medical Technology Association, Middle East and Africa

Subject: Impact of COVID-19 Situation on Regulatory Documentation

In light of the ongoing outbreak of COVID-19 which has become a major worldwide public health emergency, and continue to cause a rising number of cases around the globe every day, and while the medical technology is playing a critical role in rapidly identifying through those who are infected, ensure healthcare professionals can work safely, and that quality care is available to those who need it, particularly through three categories of health products:

- New Specific Diagnostics Tests
- Personal Protective Equipment (PPE) such as face masks, gloves, goggles, protective suits, and
- Respiratory support equipment

On a broader scope, we thought it is important to highlight key challenges currently being faced when it comes to providing proper regulatory documentation for all Medical Devices and In Vitro Diagnostics, as per initial requirements of Health Authorities, with more lockdowns being implemented in major countries, which limits the capacity and resources availability at companies, notified bodies, and other institutions, like Healthcare Authorities, embassies and Notary Public.

Site audits are also experiencing delays and postponement due to COVID-19 situation which may also affect the availability of updated audit reports.

In this respect, we would like to bring to your attention the fact that the following regulatory documents, that are usually requested for registration, renewal, importation and/or other purposes, might not be available for all medical devices and in vitro diagnostic during the current COVID-19 situation:

- Free Sale Certificate / Certificate of Foreign Government that are usually issued on request by US/EU respective authorities.
- Notarized Certificates and Documents
- Legalized Certificates and Documents
- Original documents
- Other related documents (updated audit reports, etc …).

Accordingly, we count on your understanding by accepting e-copies / soft copies of respective documents instead of the usual notarized/legalized/original versions, where e-signature could be an alternative for the ink signature and stamp at this stage.

We also call on your support by accepting commitment letters to provide other currently non-available documents in due time, and facilitating the registration, renewal and importation process of all medical technology during this critical time.

Moreover, we would like to point out the challenges foreseen in the execution of on-field post market activities within the pre-defined timelines, mainly field safety notice and product recalls, whereby most of the hospitals are currently not accepting on-site visits from company representatives.

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Finally, The Medical Technology industry, being on the forefront in supporting patients, hospitals and Healthcare Providers in these uncertain times, reaffirms its full commitment to support the authorities in the management of the crisis by enhancing what we can do best and what we can control and continuing to provide our innovative medical technologies that play a critical role in the world's healthcare system, while encouraging the authorities to work hand in hand with industry to jointly define needed practical, flexible and feasible solutions.

Yours,

Rami Rajab
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About Mecomed:

Mecomed is the medical devices, imaging and diagnostics trade association serving as the voice of international Medical Technology manufacturers across the Middle East & Africa.
Mecomed aims to bring all healthcare stakeholders together to improve the quality of people's health through the timely introduction of meaningful Medical Technology innovations, which ultimately benefits the MEA region community. We foster Good Citizenship and promote ethical business behavior, working proactively with governments, regional bodies and healthcare professionals to deliver high value solutions for better patient outcomes.

Mecomed is a member of Global Medical Technology Alliance, which includes other associations, like AdvaMed, ApacMed, MedTech Europe, Samed and others.