November 10, 2023

Mr. Teun Muller
ICAO Dangerous Goods Panel Chairman
Ministry of Infrastructure and the Environment
Directorate-General for Mobility Division for Civil Aviation
Plesmanweg 1-6
P.O. Box 20901
2500 EX The Hague, Netherlands

Re: Proposed Amendments to Air Transportation Regulations Affecting Shipments of Medical Devices

Dear Chairman Muller:

On behalf of the undersigned organizations, representing the global medical device industry, we write to express our concerns with proposed regulations on the transport of dangerous goods aboard aircraft being considered at the International Civil Aviation Organization (ICAO) Dangerous Goods Panel on November 13th, 2023. The Secretary of the Dangerous Goods Panel has filed several concerning proposals impacting international air shipments of medical devices containing batteries.

Requiring shipments of lithium ion batteries (rechargeable) packed with or contained in equipment to be shipped at the lowest practical state of charge (SOC) not to exceed 30% SOC would have significant patient care, operational, and cost implications for the medical industry, including:

- Lithium ion batteries are widely used in life-saving medical devices critical to everyday patient care. Some of these technologies include but are not limited to ventilators, intravenous pumps, pacemakers, incubators, patient monitors and defibrators. Batteries designed for medical devices must meet all medical device regulations in addition to all current transportation regulations. The higher standards in place for medical devices already provide additional safety benefits without the need for additional transportation regulation. The proposals unnecessarily subject medical devices to new air transportation requirements, presenting significant issues.

- Requiring batteries to be shipped at 30% SOC or less flatly ignores important patient safety considerations. Medical device companies ship their lithium battery-powered medical devices to patients and hospitals primarily via aircraft due to the time-critical nature of patient care; the lithium ion batteries in these devices need to be shipped at or near 100% SOC to allow for immediate use. Medical devices shipped at 30% SOC or lower will not have sufficient shelf life to go from finished manufacturing to the destination hospital with enough charge remaining to perform initial functionality tests. Without confirmation of device functionality, surgery cannot proceed. Further, hospitals and clinics often do not have the resources or specialized equipment needed to recharge devices and, even if the necessary equipment is present, many devices take hours to charge, resulting in delayed or cancelled medical procedures.

- Lithium ion batteries can also be permanently damaged if the SOC drops to 0% for an extended period; shipping a device with less than 30% SOC increases the likelihood of such an occurrence since devices may be stored for months at a time. If stored at 0% SOC for one month, lithium ion batteries used for devices like neuromodulation implants can permanently lose up to 5% capacity. Certain medical devices do not have permanent undervoltage protection, storing these devices at less than 30% SOC increases

the risk of the deep discharge that will render the device unusable. For neuromodulation implants charged to 100% SOC, the typical shelf life is about 6 months before the battery reaches 0% SOC and needs to be recharged. However, if the SOC is initially 30% or less, shelf life is reduced to only 1-2 months. Storing devices beyond this duration can permanently damage the battery with a measurable loss in capacity.

It is also important to note that medical device manufacturers are occasionally required to ship medical devices for forensic analysis. Regulatory bodies mandate that the device is not tampered with prior to appropriate analysis and specify a timeline to complete the analysis that requires air transport as the mode of shipment. As a result, the devices cannot be discharged prior to transport. Once a medical device is placed in a sterile package, it is often impossible to reduce the state of charge, other than that associated with the normal discharge rate. It is also impossible to verify the state of charge without impacting the sterility of the product.

If the 30% SOC restriction is adopted for air shipments of lithium ion battery-powered medical devices, significant changes would need to be made throughout the medical device industry, resulting in long development and recertification times in which the device is not available for the patients. Specific changes may include:

1. Changing the manufacturing process to discharge devices below 30% SOC after devices are manufactured; and
2. Changing the device itself to allow for an accurate way to determine the 30% SOC. Unlike popular consumer electronic devices, many medical devices, including implantable devices, do not have displays that allow an easy measure of SOC. Without an effective way to verify SOC, these devices would have to be shipped near 0% SOC, which would further exacerbate the recharging issue and may ultimately damage the device.

For patients requiring timely access to life-critical devices such as defibrillators, implantable medical devices (e.g., pacemakers and neuromodulators), and wearable medical devices (e.g., heart monitors, heart pumps, ventilators), a disruption to the supply chain poses serious threats to public health.

The medical device community produces state-of-the-art products that are already heavily regulated by international agencies to the highest standards of safety and effectiveness. The medical device industry is not aware of a single aviation incident involving lithium battery-powered medical devices. To the contrary, there has been consistent concern about the public health risks of restricting air shipment of medical device batteries and has allowed for exemptions for life-saving medical devices to be flown on passenger flights.

We appreciate your consideration of these issues and welcome a chance to further engage with you if there are any comments, questions, or concerns.

Respectfully,
ABHI – Association of British HealthTech Industries
ADIMECH – The Chilean Medical Device Association
AdvaMed – Advanced Medical Technology Association
APACMed-Asian Pacific Medical Technology Association
ARTED – Association of Research Based Medical Technologies Manufacturers
ASEDIM
BVMed- German Medical Technology Association

CADIEM – Argentine Chamber of Medical Technology
Confindustria Dispositivi Medici
HealthTech Ireland Association
Irish MedTech Association
KMDIA – Korea Medical Device Industry Association
MDMA – Medical Device Manufacturers Association
MDTC- Medical Device Transport Council
MedTech Canada
MITA- Medical Imaging and Technology Alliance
MTE – MedTech Europe
MTAA – Medical Technology Association of Australia
MTANZ –Medical Technology Association of New Zealand
MTaI – Medical Technology Association of Inda
Nefemed – Netherlands
SAMED – The South African Medical Technology Industry Association
SNITEM – French Association for Medical Devices
SPECTARIS – German Industry Association for Optics, Photonics, Analytical and Medical Technologies

AdvaMed
Advanced Medical Technology Association

APACMed
The voice of MedTech

BVMed German MedTech Association

MDTC
Medical Device Transport Council

MTAA Medical Technology
ASSOCIATION OF AUSTRALIA

KMDIA 사단법인 한국의료기기산업협회
Korea Medical Devices Industry Association

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