United Nations ST/SG/AC.10/C.3/2023/15

Secretariat

Distr.: General
20 April 2023

Original: English

Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods

Sixty-second session
Geneva, 3-7 July 2023
Item 3 of the provisional agenda
Listing, classification and packing

Future considerations for medical devices powered by lithium batteries

Transmitted by the Medical Device Transport Council (MDTC)*

Introduction

1. The Medical Device Transport Council (MDTC) and its members actively promote the safe transport of medical devices and their components, including lithium batteries and lithium battery-powered medical devices. Our mission is to advocate and support the development of responsible and rational regulations for the transport of medical devices and the lithium cells and batteries that power them. This document is being submitted to introduce the possibility of including four (4) new entries to the dangerous goods list specific to medical devices based on their design, manufacturing processes, regulatory oversight and their lifesaving and life-enhancing use. Prior to submitting a formal proposal MDTC is seeking the advice and input from the Sub-Committee in hopes of gaining support and suggestions for the most effective means for regulating lifesaving and life-enhancing medical devices and the batteries that power them.

2. Medical devices powered by lithium batteries are critical to the improvement of public health outcomes in all areas of the world. Given the urgent nature of medical care, it is vital that lifesaving, life-supporting and life-enhancing medical devices and their batteries be transported to patients and healthcare providers in a timely manner, often immediately, making medical device manufacturers, patients, and healthcare providers heavily dependent upon air transport. Timely access to these devices is critical to ensure effective treatment of patients and to avoid severe consequences for patients who are dependent on such medical devices for their wellbeing. These devices are designed and manufactured to be implanted or worn by humans to preserve, maintain, restore and sustain life.

3. The scope of this discussion includes medical devices intended to preserve, maintain, restore and sustain human life that are reviewed and authorized by a regulatory authority. Some examples of these medical devices include:

* A/77/6 (Sect. 20), table 20.6

(a) Implantable devices:

(i) Pacemakers;

(ii) Neuro-stimulators;

(iii) Deep-brain stimulators;

(iv) Cardiac monitors;

(v) Implantable cardiac defibrillators, etc.

(b) External devices:

(i) Wearable defibrillators;

(ii) Cardiac monitors;

(iii) Ventilators, etc.

4. MDTC is not intending to include in this discussion, medical devices that are adequately covered by regulatory provisions, such as mobility aids nor devices such as wellness trackers, smart watches or pulse/oxygen meters, which are not subject to the same rigorous regulatory requirements as the examples given above.

5. Standard ISO 13485[1] defines a medical device as follows:

"instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury;*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process;*
- *supporting or sustaining life;*
- *control of conception;*
- *disinfection of medical devices;*
- *providing information by means of in vitro examination of specimens derived from the human body;*

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means."

6. Transportation of lithium batteries has become increasingly complex especially when considering transport of lithium batteries by air. Standalone lithium-ion batteries (UN 3480) and lithium metal batteries (UN 3090) are currently forbidden as cargo on passenger carrying aircraft. This prohibition is a significant barrier to providing life-saving and life-supporting care to patients in countries and regions not regularly serviced by cargo-only aircraft. Currently, if a patient or healthcare provider needs replacement medical device batteries in an area not serviced by cargo-only aircraft, the battery supplier is forced to request a competent authority approval to ship aboard a passenger aircraft. The processing time for competent authority approvals to authorize this activity will often lead to delay in patient access for life-saving and life-supporting medical devices, leading to severe patient health consequences, including death.

7. MDTC is active and represented in numerous ongoing efforts to ensure the safe transport of lithium batteries, including the Sub-Committee's lithium battery working group, the SAE G-27 packaging group and the US DOT Lithium Battery Air Safety Advisory

[1] ISO 13485:2016. See also, GHTF/SG1/N71:2012 Definition of Terms Medical Device and In Vitro Diagnostic Medical Device, which has a similar definition of "medical device."

Committee[2] sponsored by the United States Department of Transportation. In support of public health and individual lives it is imperative that medical devices and the batteries that power them have an efficient and timely supply chain. Some discussions at these groups are considering limiting the state of charge for lithium batteries contained in or packed with equipment. With regard to medical devices, this change could jeopardize the lives of patients in need.

8. Medical devices that include batteries are often subject to additional safety standards and regulatory oversight from multiple non-transport related governmental agencies (e.g., United States Food and Drug Administration (FDA)) and these medical devices comply with standards, such as ISO 13485. In the European Union (EU), Asia, Australia and other parts of the world medical devices that include batteries must undergo a conformity assessment to ensure they are safe and perform as intended. For instance, these devices are regulated at EU Member State level, and the European Medicines Agency (EMA). Conformity assessments usually involve an audit of the manufacturer's quality system and depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device.

9. As indicated in this document, the medical device design, manufacture and tracking is under coordinated oversight by many global government agencies, this is further exhibited by the formation of the International Medical Device Regulators Forum (IMDRF)[3]. The IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence. IMDRF was established in October 2011, when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States of America, as well as the World Health Organization (WHO) met in Ottawa to address the establishment and operation of this new Forum: Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews.

10. Although these medical device regulations and standards do not specifically discuss transport safety, their strict oversight of product design, material control, process control and traceability lead to high quality products with extremely low probability of failure in conditions typical to transport. Medical device manufacturers demonstrate that their products and batteries comply with some or all the following FDA-recognized standards:

IEC 62133, Secondary Cells and Batteries Containing Alkaline or Other Non-acid Electrolytes

IEC 60086-4, Primary Batteries – Part 4: Safety of Lithium Batteries

IEC 60086-5, Primary Batteries – Part 5: Safety of Batteries with Aqueous Electrolyte

IEC 62485-X, Safety Requirements for Secondary Batteries and Battery Installations

UL 1642, Lithium batteries

UL 2054, Household and Commercial Batteries

11. Based upon the stringent regulatory requirements over the design, manufacture and tracking of medical devices including their batteries, and the fact that life-saving, life-supporting and life-enhancing medical devices are essential to ensure effective treatment of patients, we believe that such medical devices powered by lithium batteries and their replacement batteries should be provided specific UN Numbers and Proper Shipping Names. This approach would provide a pathway to ensure that these life-saving, life-supporting and life-enhancing medical devices can be delivered to patients as quickly and safely as possible, without the need of competent authority approvals.

[2] https://www.phmsa.dot.gov/hazmat/rulemakings/lithium-battery-air-safety-advisory-committee

[3] https://www.imdrf.org/documents/assessment-and-decision-process-recognition-conformity-assessment-body-conducting-medical-device-regulatory-reviews

12. MDTC will continue to work closely with all groups, including the International Civil Aviation Organization Dangerous Goods Panel (ICAO DGP) to develop responsible and rational regulations for the transportation of medical devices that include lithium cells and batteries.

Proposal

13. MDTC is not submitting an official proposal at this time. However, we believe that as lithium battery regulations continue to evolve, it will be imperative to patient health to have a path to ensure timely delivery of medical devices that include lithium batteries and replacement batteries to healthcare providers and patients who need them. We respectfully submit the following draft proposal to initiate a discussion that will likely lead to an official document at a future session.

14. In chapter 3.2 insert new entries to read as follows:

UN No.	Name and description	Class or division	Sub. haz.	UN PG	Special provisions	Limited and excepted quantities		Packagings and IBCs	
								Packing instruction	Special packing provisions
35AA	MEDICAL DEVICES CONTAINING LITHIUM ION BATTERIES or MEDICAL DEVICES PACKED WITH LITHIUM ION BATTERIES	9			188 230 310 348 377 384 387 390 XXX	0	EO	P903 P908	
35BB	MEDICAL DEVICES CONTAINING LITHIUM METAL BATTERIES or MEDICAL DEVICES PACKED WITH LITHIUM METAL BATTERIES	9			188 230 310 377 384 387 390 XXX	0	E0	P903 P908	
35CC	MEDICAL DEVICE LITHIUM METAL BATTERIES	9			188 230 310 376 377 384 387 YYY	0	E0	P903 P908	
35DD	MEDICAL DEVICE LITHIUM ION BATTERIES	9			188 230 310 348 376 377 384 387 YYY	0	E0	P903 P908	

15. In 3.3.1 add a new special provision XXX to read as follows:

"XXX This entry applies to articles that meet the definition of medical devices that include lithium ion or lithium metal batteries. These medical devices shall be intended to sustain, maintain, restore, or preserve human life and reviewed and authorized by a regulatory authority."

16. In 3.3.1 add a new special provision YYY to read as follows:

"YYY This entry applies to lithium ion batteries and lithium metal batteries intended for use within medical devices. These batteries must be tested in accordance with the *Manual of Tests and Criteria* section 38.3 or transported under the provisions of special provision 310. The packaging of lithium ion and lithium metal batteries designed for use in medical devices shall meet the requirements of packing instruction P911 and include the following marking: "Medical device batteries – Emergency"."

17. Amend Appendix B, Glossary of Terms to insert the ISO 13485 "medical device" definition as follows:

*"**Medical device***

Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

diagnosis, prevention, monitoring, treatment or alleviation of disease;

diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

investigation, replacement, modification, or support of the anatomy or of a physiological process;

supporting or sustaining life;

control of conception;

disinfection of medical devices;

providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means."

18. The entry name in the alphabetical index should be amended as follows:

Name and description	**Class**	**UN Number**
MEDICAL DEVICES CONTAINING LITHIUM ION BATTERIES or MEDICAL DEVICES PACKED WITH LITHIUM ION BATTERIES	9	35AA
MEDICAL DEVICES CONTAINING LITHIUM METAL BATTERIES or MEDICAL DEVICES PACKED WITH LITHIUM METAL BATTERIES	9	35BB
MEDICAL DEVICE LITHIUM METAL BATTERIES	9	35CC
MEDICAL DEVICE LITHIUM ION BATTERIES.	9	35DD