

27-JAN-2021

Changes to labels for medical device batteries

Dear Valued Alpha Source Customer,

The purpose of this letter is to inform you about the changes we made to our labels for medical device batteries. We updated our labels to comply to Harmonization Symbol Standard ISO15223-1.

What did we update?

- Included the Manufactured symbol next to our name and address
- Included the Temperature Limit symbol for storage control
- Updated the Label Revision for better quality control
- Removed Rx symbol and CE mark on labels that were not associated to the medical device

Why did we update the labels?

- The labels were not in compliance with Harmonization Symbol Standard ISO 15223-1.
- We did not have some of the symbols required on the label and removed symbols that were not associated to the device.

When is the change effective?

- The changes are effective immediately on future orders.

Do the label changes affect how the battery is manufactured/shipped?

- No, the label changes were made to comply and display information that are required for the medical device battery. There were no changes or modifications to the device itself.

Thank you for your attention to this important matter, and for your business with Alpha Source Inc. Please contact me if you have any questions or concerns.

Respectfully,



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