



**Philips Healthcare**

**IMPORTANT REMINDER – ACTION REQUIRED**

Dear Sir/Madam;

This is an important reminder that world-wide regulatory agencies, including the United States Food and Drug Administration, require senior living communities providing a Philips Personal Help Button to residents to report qualified medical device complaints and events associated with its products, regardless of where in the world the complaint or event occurred.

As a provider of Philips products to your residents, it is therefore necessary for you to provide Philips with immediate and accurate reporting on **any** instance of a Philips device involved in:

- Death – regardless of the cause (this includes user error),
- Serious injury, or
- A device malfunction that could lead to death or injury should it reoccur.

Philips is dedicated to providing quality medical devices to its customers and takes great pride in its standing as a compliant medical device manufacturer. Together, with your assistance, we can meet our legal obligations in reporting these qualified medical device events to ensure we maintain a safe and healthy environment for our collective customers.

Philips values its relationships with our providers. We ask that you take immediate action to ensure your organization is acting within the required legal framework and make any appropriate changes necessary to meet your regulatory reporting obligations.

If you need any further information or support concerning this issue, please contact Philips at 508-988-1780.

Sincerely,

Philips Lifeline