

January, 2023

Dear Valued Customer,

As the equipment manufacturer, Getinge USA Inc. (Getinge) is the sole-source supplier of factory authorized OEM (original equipment manufacturer) replacement parts and accessories for your equipment. Getinge OEM parts are tested for performance, longevity, and cost effectiveness. They are service parts which meet OEM operational requirements and provide the best performance life in application of use.

As the service division of the original equipment manufacturer, Getinge's field service team is held to a higher service standard. Getinge products are cleared by the FDA under the guidelines of the 510K approval process. When serviced by a Getinge service program over its lifetime, the equipment will meet OEM specifications.

Getinge Care Service is the sole-source for OEM technicians who are trained and certified to perform scheduled and unscheduled maintenance on Getinge equipment. To assure customer satisfaction and ensure equipment performance, Getinge has a Field Service Escalation process. The purpose of which is to establish an effective method for escalating a customer concern or problem to the necessary management level. The process details levels of service support from the field starting with support from a regional senior service representative to a Service Operations Specialist. The process has triggers based upon the elapsed time of implementing the repair.

### **ISO Certification**

Getinge has maintained an uninterrupted certification to the ISO standards for quality management systems 9001 and 13485 since 2006. ISO 13485 specifies the requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

### **Complaint Handling**

As required by the Code of Federal Regulations, 21 CFR part 803, Getinge defines a complaint as any alleged deficiency as defined by the customer. We also consider all unplanned (non-preventive maintenance) service calls complaints. Each time an unplanned service call is conducted the information is transferred into a Getinge Global complaint system. Each complaint is reviewed and each investigated. The highest level of our organization has visibility to this system. The system also has a track and trend feature, enabling our equipment design

team and manufacturer(s) to anticipate potential problems before they result in customer downtime. Tracking and trending provides an input to continual product/service improvement.

### **Quality Measures**

Getinge has identified internal and external KPI (Key Performance Indicators) of which customer feedback is crucial. Customer satisfaction is measured in variety of ways. Getinge utilizes md Buylane whose independent metrics provide an unbiased report card.

### **Service Metrics**

- Response time for service requests – Measured and reviewed regularly is our commitment to a PM Schedules - A measurement and review of Getinge's Service performance to on-time preventative maintenance schedules.
- First Time Fix- The newest of the service metrics intended to drive fix it right the first time.

Getinge provides the power of a global company serving our customers for over 125 years. We think you will agree that our courteous, responsive Customer Support Center staff and our North American network of trained local service representative will enable you to get the most from your equipment investment.

Call us at 888-627-8383