

Quality Assurance and Control Program

AMG Equipment is a redistributor of surgical supplies to healthcare facilities and relief organizations throughout the United States and all over the world. AMG Equipment partners with hospitals and surgery centers to assist them in recovering monies spent on Prescription Medical Devices (“PMDs”) by purchasing their in-date, unused, surgical disposable inventory. On the other hand, AMG Equipment provides supplemental cost-savings to hospitals and surgery centers who are sourcing and purchasing these same PMDs to lower their med/surg spending.

Though companies like AMG Equipment are not regulated by the Food and Drug Administration (“FDA”), to comply with the FDA’s regulatory decisions to limit the tracking, registration and listing requirements for distributors of PMDs, AMG Equipment adheres to a Quality Assurance & Control Program that includes specific sourcing, selling, and quality control best practices. These best practices were designed to significantly reduce the likelihood that AMG Equipment could unintentionally purchase products from a seller that could not demonstrate its legitimate ownership. AMG Equipment purchases inventory from licensed facilities, including hospitals, ambulatory surgery centers, and medical device distributors.

The best practices that are implemented include the following:

- I. restrictions on eligible vendors;
- II. required paperwork for all transactions including signed purchase offer, and invoice;
- III. quality control procedures to ensure the maintenance of safety and efficacy upon receipt, storage and distribution.

AMG Equipment’s warehouse team follows strict quality control processes to assure product integrity and accuracy. AMG Equipment strives to provide the best possible service through an advanced inventory tracking. AMG Equipment distributes inventory of surgical disposables to integrated delivery networks, community and rural hospitals, medical universities, as well as ambulatory and same-day surgery centers on a daily basis that trust in the quality of product provided.

Quality Control

AMG Equipment’s staff follows strict guidelines when receiving and shipping surgical supplies:

- I. Upon receipt, each item is individually inspected to ensure it meets quality assurance standards. Our inspection process includes but is not limited to:
 - a. OEM Packaging Inspection: Each item received is thoroughly checked for visual OEM package integrity. AMG Equipment carefully inspects each package to ensure that the contents accurately reflect the appropriate manufacturer product code, lot number, and expiration date. Each package is inspected to make sure that it is clear from any blemishes and/or damage.
 - b. Individual Product Inspection: AMG Equipment physically inspects each item to ensure that the integrity of the product has not been damaged during the shipping process.

- c. Lot Number and Expiration Date Inspection: AMG Equipment inspects each unit to ensure that the product is in-date. In addition, AMG Equipment inspects and records each individual lot number to ensure the product received is not subject to recall.
- d. Temperature Gauge Inspection: Upon receipt and delivery, temperature indicators that are located on climate-controlled disposables are verified to ensure product integrity.

Upon completion of the quality control process, each individual unit is logged into an advanced inventory tracking software with lot number and expiration date for strict tracking purposes.

Cleanliness

The storage facility is cleaned and free of waste on a daily basis. No smoking, eating, or drinking is permitted in areas used for storage and handling. The storage area is designed and equipped to prevent the entry of insects and other pests.

Exposure to Outside Elements

The storage facility is designed to protect products from water infiltration as well as sunlight exposure. The reception and packing areas are segregated from the storage site to eliminate unnecessary exposure.

Data Tracking

Although not required by the FDA, the AMG Equipment quality assurance program exceeds requirements by voluntarily tracking and recording lot numbers. AMG Equipment's inventory system tracks Expiration, Product Number, and Lot number to ensure full traceability of product entering and exiting its warehouse.

Recalls

AMG Equipment continuously reviews products for recall. In the event of a recall, the product is identified, segregated, and destroyed.

When a recall alert is received at AMG Equipment, both voluntary from a seller and involuntary through the FDA MAUDE Database: (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>) AMG Equipment immediately contacts appropriate parties.

FDA Searchable Recall Database:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

Link to RSS feeds for Email Alerts regarding Recalls

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm>

When a recall alert is received at AMG Equipment both voluntary from a seller and involuntary through the FDA through MAUDE Database. We immediately load it into our system to contact our second party buyers.

MAUDE Database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Selling Protocols

AMG Equipment enforces the following “Selling Protocols” to ensure the safety and efficiency of selling PMDs in a secondary market:

- I. The customer must be a person or entity with authority to own the merchandise – pursuant to Title 21, United States Code.
 - a. The customer may be a provider of medical services (ex. hospital, clinic, surgical center, distributor).
- II. All sellers must be able to prove they have good and marketable title to the merchandise being sold and that the product being sold has been stored and maintained properly. Facilities must be willing to demonstrate to AMG Equipment upon request:
 - a. A record of the purchase of the merchandise together with a copy of the invoice and evidence of payment for the merchandise.
 - i. The record must show that the merchandise was purchased from a person or entity with authority to own the merchandise – pursuant to Title 21 of the United States Code.
 - ii. An inventory control sheet of the seller printed on the stationery of the seller from whom the merchandise was purchased and bearing all marks typical of such documents - such as inventory control numbers, storage locations, purchase dates, manufacturer name, expiration dates.
- III. All sales made by AMG Equipment must include the following documentation:
 - a. A purchase order addressed to AMG Equipment for the merchandise. The purchase order must bear the customer’s name and full business address.
 - b. All AMG Equipment sales are concluded with an invoice on AMG Equipment company stationery.
 - c. All AMG Equipment sales must be paid by company check or cashier’s check of or by the customer and the check payable to AMG Equipment. AMG Equipment also accepts wire transfers and credit cards.

Corporate Responsibility

If you would like to donate your surplus supplies, AMG Equipment works with relief organizations that specialize in providing and redistributing surgical products to developing countries across the world. By donating your non-moving, unwanted, or recently expired surgical supplies, you are able to obtain tax write-offs, while providing supplies to those without the means to get it themselves.

AMG Equipment partners with Faith in Action to provide medical products on a global level. In working with domestic hospitals and surgery centers, AMG Equipment frequently uncovers products unsuitable for domestic placement, but suitable for use in international health care providers, particularly in the developing world.

Faith in Action is a not-for-profit corporation that recovers surplus medical products and distributes them to relief agencies working in developing nations. The medical products we recover provide medical humanitarian aid and improve healthcare access in impoverished communities while preventing these life-saving materials from going to waste. To read more about Faith in Action, please visit www.faithinaction.org.