MEDICAL EQUIPMENT

These product category descriptions are to be used in conjunction with the "Overview of ARL's Listing, Labeling and Follow-Up Inspection Services" (LSc001) which details ARL's system requirements for obtaining a listed product certification.

This includes the following subcategories:

- ***Medical Electrical Equipment and Medical Electrical Systems***

Medical Electrical Equipment and Medical Electrical Systems

This category includes products that incorporate the basic safety and essential performance of medical electrical equipment and medical electrical systems, hereafter referred to as ME equipment and ME systems.

This category also includes equipment used for compensation or alleviation of disease, injury or disability. This category does not include:

In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT.

implantable parts of active implantable medical devices covered by ISO 14708-1 3).

implantable parts of active implantable medical devices covered by the ISO 14708 series; or

medical gas pipeline systems covered by ISO 7396-1.

The object of this category is to specify general requirements and to serve as the basis for the application of particular standards as appropriate.

These products comply with ARL requirements which include applicable sections of **IEC/EN/CSA/UL/ANSI/AAMI ES60601-1 Medical electrical equipment, part 1: general requirements for safety (excluding sections 5, 6, and 7 and sub clauses 43.2 and 48).**
Each listed product is marked with the name or trademark of the (manufacturer) or vendor, a distinctive type, style, model or catalog designation, date code, electrical ratings, electrical hazard warnings, and other markings and cautionary warnings as required for specific types of products.

A product that contains features, characteristics, components, materials, or systems new or different from those covered by the requirements of the standard, and that involve a risk of fire, electric shock, or injury to persons, have been evaluated using the appropriate additional component and end-product requirements as determined necessary to maintain the acceptable level of safety as originally anticipated by the intent of the standard. A product whose features, characteristics, components, materials, or systems conflict with specific provisions of the standard have been judged to be in non-compliance with the standard.

Only products which properly bear the ARL Listing Mark (Label) are considered Listed by ARL.