A-A-51597A
15 June 1990
SUPERSEDING
A-A-51597
22 August 1986

COMMERCIAL ITEM DESCRIPTION

ELECTRODE, ELECTROCARDIOGRAPH

The General Services Administration has authorized the use of this commercial item description.

This commercial item description covers a disposable pregelled electrocardiographic electrode suitable for cardiac monitoring.

Salient characteristics:

The electrocardiograph electrode shall be a low impedance, disposable, pregelled, adhesive foam, electrode with a silver/silver chloride sensor and a snap connector.

Construction shall be of soft, pliable materials to provide maximum patient comfort. Adhesive shall be non-irritating to the skin.

Electrode shall be approximately 55 mm in diameter.

Electrode shall permit low DC offset and minimum noise artifact recording when applied properly.

Electrode shall comply with the applicable requirements of American National Standard for Pregelled ECG Disposable Electrodes (ANSI/AAMI EC12).

Electrode shall have a minimum 24 month shelf life. Not less than 20 months of the expiration dating period shall remain at time of delivery to the Government.

Workmanship. The electrocardiograph electrode shall be free from defects which detract from its appearance or impair its serviceability.

AMSC N/A FSC 6515

Unit. Package (PG). One package containing ten (10) packs of four (4) electrodes per pack (40 electrodes), as specified, constitutes one unit.

Quality Assurance Provisions.

Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the contractor is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or purchase order, the contractor may use his own or any facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records. Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of three years after delivery of the supplies to which such records relate.

Inspection. Inspection, as used herein, is defined as both examination (such as visual or auditory investigation without the use of special laboratory appliances or procedures) and testing (determination by technical means of physical and chemical properties) of the item.

Metric products. Products manufactured to metric dimensions will be considered on an equal basis with those manufactured using inch-pound units, providing they fall within the tolerances specified using conversion tables contained in the latest revision of Federal Standard 376, and all other requirements of this document are met.

If a product is manufactured to metric dimensions and those dimensions exceed the tolerances specified in the inch/pound units, a request should be made to the contracting officer to determine if the product is acceptable.

The contracting officer has the option of accepting or rejecting the product.

Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this description and conforms to the producers' own drawings, specifications, standards, and quality assurance practices. The Government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

Regulatory requirements.

Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and local statutes, ordinances, and regulations.

Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Public Law 94-580, as amended, and as implemented by Federal Acquisition Regulation Subpart 23.4 to the maximum extent practical.

Preservation, packaging, packing, labeling, and marking. Unless otherwise specified, preservation, packaging, and packing shall be to a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., involving shipment from the supply source to the receiving activity, plus reshipment from receiving activity, and shall conform to applicable carrier's rules and regulations. Intermediate and exterior package quantities and labeling and marking shall be as specified in the contract and/or order.

NOTE: The following National Stock Number is covered by this document:

6515-01-149-3571

Ordering data. Intermediate/exterior package quantities, labeling, and marking must be specified in the contract and/or order.

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MILITARY INTERESTS:

Custodians:

Army - MD
Navy - MS
Air Force - 03

Preparing Activity:

DoD - MB

Agent:

DLA-DM

CIVIL AGENCY COORDINATING ACTIVITIES:

VA-OSS
PHS
FDA-MPQAS

Project No. 6515-4712

Location: CID/ELECTRODE/H16-3