

Contract Line Item Numbers & Salient Characteristics Attachment 1

This requirement will be IAW FAR clause 52.211-6, "Brand Name or Equal" which requires that the offeror indicate each product that is being offered as an "equal" product. For each equal product, the offeror must include a description reflecting the characteristics and level of quality that will satisfy the salient physical, functional, or performance characteristics of the equal product(s) specified in the solicitation. The offeror also must clearly identify the item by brand name (if any) and make/model number. Finally, the offeror must include descriptive literature, such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the contracting officer, and clearly describe any modifications it plans to make to a product to make it conform to the solicitation requirements.

Gaseous Plasma Sterilizing Units

Salient Characteristics (SC) Literature Review

SC 1 Sterilizing Units: Gaseous Plasma must achieve total inactivation of microorganisms that are or may be present on medical devices using vapors or gases in plasma state (a form of matter that includes electrons and positive ions usually resulting from the application of a strong electromagnetic (e.g., radio frequency) field).

SC 2 Sterilizing Units: Gaseous Plasma must be capable of safely and effectively processing metal and non-metal instruments that are sensitive to high temperature and humidity (e.g., must process cameras, rigid scopes, light cords, batteries, power drills, dopplers, electrocautery instruments, lasers hand pieces and fibers, ophthalmic lenses, patient lead cables, and ultrasound probes).

SC 3 Sterilizing Units: Gaseous Plasma must include a minimum usable treatment chamber of 3 cubic feet or 85 liters with a minimum of two shelves on which the devices to be sterilized are placed.

SC 4 Sterilizing Units: Gaseous Plasma must include a means to introduce the vapor (e.g., hydrogen peroxide, H₂O₂) into the chamber.

SC 5 Sterilizing Units: Gaseous Plasma must include electrodes that are activated to convert the vapor to plasma; a radio-frequency generator; and controls to start/stop automated cycles of the procedure.

SC 6 Sterilizing Units: Gaseous Plasma must provide an integral evacuation system to eliminate all residues without the need for any additional processing prior to use of the items.

SC 7 Sterilizing Units: Gaseous Plasma must process all loads in 60 minutes or less and have an option to process a minimum of 1 flexible scope in a cycle not exceeding 45 minutes.

SC 1 through SC 7 are associated with the following CLINS: 0001 to 0004, 0007, 0008, 0011, 0015, 0016, 0018, 0019, and 0021.

CLIN	Manufacturer	Part Number	Description
0001	Johnson and Johnson (STERRAD)	10104-005	100NX Sterilization System with ALLClear Technology, single-door unit, STANDARD & FLEX cycles, includes installation Standard: sterilizes most general surgical instruments, Time: 47 minutes, Lumen Claims: diameter: ≥0.7 mm; length: ≤500 mm. Flex: sterilizes up to 2 single-channel flexible endoscopes, Time: 42 minutes, Lumen Claims: diameter: ≥1 mm; length: ≤850 mm-System Dimensions (max): Height: 1800 mm Width: 775 mm Depth: single door: 1055mm.
0002	Johnson and Johnson (STERRAD)	10104-006	100NX Sterilization System with ALLClear Technology, double-door unit, STANDARD & FLEX cycles, includes installation Standard: sterilizes most general surgical instruments, Time: 47 minutes, Lumen Claims: diameter: ≥0.7 mm; length: ≤500 mmFlex: sterilizes up to 2 single-channel flexible endoscopes, Time: 42 minutes, Lumen Claims: diameter: ≥1 mm; length: ≤850 mm-System Dimensions (max): Height: 1800 mm Width: 775 mm Depth: double door: 1095 mm.

0003	Johnson and Johnson (STERRAD)	10104-007	100NX Sterilization System with ALLClear Technology, single-door unit, STANDARD, FLEX and DUO cycles, includes installation, Standard: sterilizes most general surgical instruments, Time: 47 minutes, Lumen Claims: diameter: ≥ 0.7 mm; length: ≤ 500 mm Flex: sterilizes up to 2 single-channel flexible endoscopes, Time: 42 minutes, Lumen Claims: diameter: ≥ 1 mm; length: ≤ 850 mm, Duo: sterilizes cameras and up to 2 single-channel flexible endoscopes, Time: 60 minutes, Lumen Claims: diameter: ≥ 1 mm; length: ≤ 875 mm System Dimensions (max): Height: 1800 mm Width: 775 mm Depth: single door: 1055mm.
0004	Johnson and Johnson (STERRAD)	10104-008	100NX Sterilization System with ALLClear Technology, double-door unit, STANDARD, FLEX, and DUO cycles, includes installation, Standard: sterilizes most general surgical instruments, Time: 47 minutes, Lumen Claims: diameter: ≥ 0.7 mm; length: ≤ 500 mm Flex: sterilizes up to 2 single-channel flexible endoscopes, Time: 42 minutes, Lumen Claims: diameter: ≥ 1 mm; length: ≤ 850 mm, Duo: sterilizes cameras and up to 2 single-channel flexible endoscopes, Time: 60 minutes, Lumen Claims: diameter: ≥ 1 mm; length: ≤ 875 mm System Dimensions (max): Height: 1800 mm Width: 775 mm Depth: double door: 1095mm.
0007	Johnson and Johnson (STERRAD)	10135	100NX System EXPRESS Cycle Kit Express: sterilizes da Vinci® 3-D endoscopes and other delicate instruments without lumens, TIME: 24 minutes, Lumen Claims: Express: nonlumen sterilization only.
0008	Johnson and Johnson (STERRAD)	10137	100NX System DUO Cycle (for an existing STERRAD 100NX System)
0011	Johnson and Johnson (STERRAD)	10033-004	STERRAD NX Sterilization System with All Clear Technology, STANDARD & ADVANCED cycles, includes installation Standard: sterilizes most general surgical instruments Advanced: sterilizes single-channel rigid endoscopes or up to 1 single-channel flexible endoscope Time Standard: 28 minutes Advanced: 38 minutes Lumen claims Standard: single-channel stainless steel lumens diameter: ≥ 1 mm; length: ≤ 150 mm OR diameter: ≥ 2 mm; length: ≤ 400 mm Advanced: single-channel stainless steel lumens diameter: ≥ 1 mm; length: ≤ 500 mm OR single-channel PE/PTFE flexible endoscopes diameter: ≥ 1 mm; length: ≤ 850 mm.
0015	Johnson and Johnson (STERRAD)	10104	100NX Sterilization System, single-door unit STANDARD Cycle: 47 minutes FLEX Cycle: 42 minutes Weight: 425 kg single-door.
0016	Johnson and Johnson (STERRAD)	10104-002	100NX Sterilization System, double-door unit STANDARD Cycle: 47 minutes FLEX Cycle: 42 minutes Weight: 457 kg double-door.
0018	Johnson and Johnson (STERRAD)	10134	100NX Sterilization System Express Cycle EXPRESS Cycle: 24 minutes.
0019	Johnson and Johnson (STERRAD)	10136	100NX Sterilization System DUO Cycle DUO Cycle: 60 minutes.
0021	Johnson and Johnson (STERRAD)	10033	STERRAD NX Sterilization System Standard/Advanced cycles Cycle Time Standard 28/ Advanced 38 minutes.

SC 8 Sterilizing Units: Gaseous Plasma must meet or exceed EN ISO 14937 sterilization standards

SC8 is associated with the following CLIN: 0017

CLIN	Manufacturer	Part Number	Description
0017	Johnson and Johnson (STERRAD)	10140	Independent Monitoring System (IMS) Enables remote, independent monitoring of all processes and is available as an option.

ALL other CLINS are accessories to the Gaseous Plasma Sterilization Unit as a whole; they do not individually apply to the above stated SCs.