

Grouping, packaging and labeling:

Goods must be grouped and packaged according to three (3) different Packaging Configurations: CHU, CHRR and CHRD.

Each outer packaging must be labeled clearly indicating "Instrumental for CHU", "Instrumental for CHRR" or "Instrumental for CHRD", with at least 400 cm² label (I.E. 20x20cm).

The offeror must send with the offer a list of the elements that each pallet will contain.

Shall be delivered: 10 units of CHU Packaging Configuration, 10 units of CHRR Packaging Configuration and 13 units of CHRD Packaging Configuration.

Instrumental packaging:

Each CHU Packaging Configuration of Instrumental will contain the following items, in the indicated quantities:

Code	Items	Quantities of each item included in the CHU Packaging
OTI-06	Cesarean box	1
OTI-08	Hysterectomy box	1
OTI-09	Laparotomy box	1
OTI-11	Small surgery box	1
OTI-12	Dressing set	2
OTI-13	Surgical toilet set	2
OTI-17	Cotton box	2
OTI-19	Kit vaginal speculum	2
OTI-20	Spatula	1

Each CHRR Packaging Configuration of Instrumental will contain the following items, in the indicated quantities:

Code	Items	Quantities of each item included in the CHRR Packaging
OTI-17	Cotton box	1
OTI-19	Kit vaginal speculum	1
OTI-45	Simple delivery box	1
OTI-49	Spatula / forceps	1

Each CHRD Packaging Configuration of Instrumental will contain the following items, in the indicated quantities:

Code	Items	Quantities of each item included in the CHRD Packaging
OTI-06	Cesarean box	1
OTI-08	Hysterectomy box	1
OTI-09	Laparotomy box	1
OTI-11	Small surgery box	1
OTI-12	Dressing set	1
OTI-13	Surgical toilet set	1
OTI-17	Cotton box	1
OTI-19	Kit vaginal speculum	1
OTI-20	Spatula	1

The total quantity of each item is summarized below, considering 10 units of CHU Packaging Configuration, 10 units of CHRR Packaging Configuration and 13 units of CHRD Packaging Configuration.

Code	Items	Items included in each of 10 CHU	Items included in each of 10 CHRR	Items included in each of 13 CHRD	Total quantities
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		Packaging Configuration	Packaging Configuration	Packaging Configuration	
OTI-06	Cesarean box	1		1	23
OTI-08	Hysterectomy box	1		1	23
OTI-09	Laparotomy box	1		1	23
OTI-11	Small surgery box	1		1	23
OTI-12	Dressing set	2		1	33
OTI-13	Surgical toilet set	2		1	33
OTI-14	Instrument trolley	2		1	33
OTI-17	Cotton box	2	1	1	43
OTI-19	Kit vaginal speculum	2	1	1	43
OTI-20	Spatula	1		1	23
OTI-45	Simple delivery box		1		10
OTI-49	Spatula / forceps		1		10

Goods must be shipped disassembled to their minimum size, to minimize package size, but in such a way that they can be easily assembled by the user, following the assembling instructions and using the assembling tools that shall be provided with each package, if applicable.

More than one package can be included in the same pallet. If so, each Packaging Configuration of type CHU, CHRR and CHRD for Instrumental must be individually packaged and easy to separate.

General description of packaging:

International Air Transport Association (IATA) approved, if applicable.

Transport packaging organized into: primary and outer packaging.

Primary packaging:

Each product will have its primary packaging that will guarantee safe transportation and distribution within the country, and prevents the penetration of dust, water and humidity.

Outer packaging:

Individual packages will be grouped as above indicated in CHU, CHRR and CHRD quantities of items, and assembled as per specified Packaging Configuration to ensure safe transportation and distribution within the country.

Each group of products will be packed in high-resistance outer boxes, to guarantee the protection of the product throughout the supply chain by air, sea and/or land to the final destinations.

The package must be capable of resisting the effects of any acceleration, vibration or resonance of vibrations that may occur under normal conditions of transport, without deterioration of the integrity of the package as a whole or of the goods inside.

Must provide protection to products against dust, and resist temperatures up to 40°C and humidity of at least 90%.

The cost of packaging will be included in the offered cost of the products.

The deliveries should be packed and palletized in the most cost-effective way to minimize freight costs.

General description of labeling:

When the products are classified as medical devices the product labeling shall meet the requirements described in the Global Harmonization Task Force document: GHTF/SG1/N70:2011: Label and instruction for Use for Medical Devices.

The languages of the label and the product documentation should be English and French.

The primary packaging label shall be in French for each unit or multiple devices and shall include the following data:

- Product name, model name, reference of the manufacturer, configuration and list of included accessories;
- Names of the manufacturer and of the distributor;
- Quantity of products per package;
- Manufacturing date;
- The lot code/lot number or serial number of the medical device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as applicable;
- Cautionary statements.

The outer packaging label must include the following data:

- Package type name: "Instrumental for *Packaging Configuration*"; according to as above indicated in General organization of the packages;
- List of products and quantities contained;
- Name and address of the manufacturer and/or distributor;
- Cautionary statements.