Question: What will be the Fee and Document requirement for medical devices and IVDs under grouping guidelines under Medical Devices Rules 2017?

Answer: The Fee and Document requirement for IVDs under grouping guidelines are as under & applicable only for the medical devices & IVDs regulated under Medical Devices Rules 2017.

(1) Fee and Document requirement for medical devices other than IVDs:

Sr. No.	Type	Criteria	Fees/ Documents
1	Single	1) Sold as a distinct packaged entity. 2) Does not meet criteria for family, System, or Group.	1) Separate fee for each single device. 2) Separate documentation for each single device.
2	Family	1) Is from the same registration or license holder. 2) Is of same risk classification class. 3) Has a common intended use. 4) Has the same design & manufacturing process. 5) Has variations that are within the scope of the **permissible variants**.	1) Single fee for a family. 2) Common DMF.
3	System	1) Are from the same registration or license holder. 2) Intended to be used in combination to complete a specific intended purpose. 3) Compatible when used as a system. 4) Sold under a single, proprietary System name.	1) If a system is proposed to be imported or manufactured for sale as Single Unit Pack only but not as individual components: (i) Single fee for the system. (ii) Separate documentation for each of the componentsof the system. 2) If the System is proposed to be imported or

			manufactured for sale as Single Unit Pack or as individual component: (i) Separate fee for each of the components of the system. (ii) Separate documentation for each of the componentsof the system.
4	Group	1. Collection of two or more medical device from different manufacturers 2. Single Propriety Group name 3. Labelled and supplied in a single packaged unit by the manufacturer 4. Common intended use	1. Single fees 2. Documentation with respect to each medical device need to be provided.

Following are the examples of the Grouping categories for medical devices other than IVDs:

Family:

- Condoms that differ in colour, size and texture but are manufactured from the same material, using common manufacturing process and share a common intended purpose can be grouped as a FAMILY.
- IV administrative sets that differ in features such as safety wings and length of tubing, but are manufactured from the same material, common manufacturing process and share a common intended purpose can be grouped as a FAMILY.
- Steerable guidewires that are available in various lengths and possess various tip shapes and tip flexibilities can be grouped as a FAMILY if their variations fall within the scope of permissible variants.
- Cardiac catheters that are available in a different number of lumens, lengths and diameters can be grouped as a FAMILY.
- Contact lenses with additional features of UV protection can be grouped as a FAMILY, as this feature does not affect the basic design and manufacturing of the lens.
- Contact lenses are available as toric lens or spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as members of a FAMILY.

Permissible variants:

LIST OF PERMISSIBLE VARIANTS IN A FAMILY

Specific products	Permissible variants
Blood Bags	(i) Anticoagulants with same composition but different concentrations (ii) Additives (different composition and concentrations)
Catheter	(i) Number of lumens in catheter (ii) Material of catheter: PVC (polyvinylchloride), PU (polyurethane), nylon and silicone (iii) Curvature (iv) Coating material for lubrication
Condoms	(i) Texture (ii) Flavour
Defibrillators	Automatic or semi-automatic
Dental brackets	Material of bracket
Dental handpieces	(i) Rotational speed (ii) Material of handpiece
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Gloves	Powdered or powder-free
Guide wire	With or without inert coating material
Orthopaedic/ Dental Implants	(i) Cemented or non-cemented fixation (ii) Collar
Intra-ocular Lens	(i) Monofocal or Multifocal (ii) Multi-piece or Single-piece (iii) Aspheric or Spheric
Implantable Pulse Generators	Number of Chambers (Cardio)
IV Cannula	(i) Presence of injection port (ii) Presence of safety wing

Polymer products	With or without plasticisers (e.g. DEHP)
Stent	(i) Delivery system, that is over-the-wire or through the scope (ii) Flaps, Flares or sleeves
Suture	(i) Number of strands (ii) Pledgets (iii) Loops (iv) Dyes
Tracheal Tube *(endotracheal tube, tracheostomy tube)*	With or without cuff
Wound Dressings	Different formats (e.g. solution, creams, gels loaded onto pads, etc)

System:

A hip replacement SYSTEM comprising of femoral and acetabular components can be grouped as a SYSTEM. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.

A catheter placement set/kit comprising of scalpels, syringes, needles, surgical gloves, gauze, drapes and flushing solution that is validated for compatibility and assembled by a single product owner under a single SYSTEM name for use in combination during a surgical catheter placement procedure can be grouped as a SYSTEM.

Group:

A **first aid kit** consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package for a common medical purpose by a product owner, can be grouped as a GROUP.

(2) Fee and Document requirement for IVDs:

Sr. No.	Type	Criteria	Fees/ Documents
1	Single	3) Sold as a distinct packaged entity. 4) Does not meet criteria for family, IVD test kit, System, IVD cluster or Group.	1) Separate fee for each single device. 2) Separate documentation for each single device.
2	Family	6) Is from the same registration or license holder. 7) Is of same risk classification class. 8) Has a common intended use. 9) Has the same design & manufacturing process. 10) Has variations that are within the scope of the permissible variants.	1) Common fee for a family. 2) Common DMF.
3	IVD Cluster	1) Is from the same registration or license holder. 2) Of a common methodology but may have different intended use. 3) Sold under a single, proprietary name. 4) Compatible when used as a test kit.	1) Separate Fee for each product. 2) Common DMF. 3) Details of each product to be registered.
4	IVD Test Kit	1) Is from the same registration or license holder. 2) Intended to be used in combination to complete a specific intended purpose. 3) Reagents and articles compatible as an IVD test kit (exclude instruments). 4) Sold under a single, proprietary Test Kit name.	1) If the IVD test Kit is proposed to be imported or manufactured for sale as Single Unit Pack only but not as individual products: (i) Single fee for the IVD Test Kit. (ii) Separate documentation for each of the constituents IVD Test Kit. 2) If the IVD test Kit is proposed to be imported or sold as Single Unit Pack or as individual products: (iii) Separate fee for each of the constituents of the IVD Test Kit.

			(iv) Separate documentation for each of the constituents IVD Test Kit.
5	System	1) Are from the same registration or license holder. 2) Intended to be used in combination to complete a specific intended purpose. 3) Compatible when used as a system. 4) Sold under a single, proprietary System name.	1) If the a system is proposed to be imported or manufactured for sale as Single Unit Pack only but not as individual components: (i) Single fee for the system. (ii) Separate documentation for each of the components of the system. 2) If the System is proposed to be imported or manufactured for sale as Single Unit Pack or as individual component: (i) Separate fee for each of the components of the system. (ii) Separate documentation for each of the components of the system.
6	Group	Shall be not applicable to IVD.	-

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