

Government of India
Ministry of Health and Family Welfare
(Department of Health and Family Welfare)

New Delhi, March, 2018

Grouping Guidelines for Medical Devices Applications

In pursuance of rule 5 of the Medical Devices Rules, 2017 the Central Government hereby notifies the following guidelines in respect grouping of Medical Devices for a person who applies for licence to import or manufacture for sale or distribution of medical devices, namely,-

1. Application for license:

- (1) Application for licence to import or manufacture for sale or distribution, sell, stock or offer for sale or distribution of medical device shall be made as specified under respective Form to the Appendix to Medical Devices Rules, 2017.
- (2) The applicant may group medical devices having same or similar intended uses or commonality of technology and submitted in a single application. The grouping of medical devices is for purpose of submission of single application for license to import or manufacture in the following manner:-

(i) Single

- a. A single medical device is a medical device sold as a distinct packaged entity and does not meet the criteria for family, IVD test kit, system, IVD cluster or a group. It may be sold in a range of package sizes.
- b. The medical devices that cannot be assigned to family, IVD test kit, system, IVD cluster or a group must be licensed separately.
- c. The medical devices which are a part of a group must be licensed separately before it sold separately as individual medical devices.

Illustration:

- A. Condoms are sold in package of 3, 10 or 16 can be licensed a single medical device applications.
- B. A company that assembles and licenced a first aid kit has now decided to also supply each of medical devices in the first aid kit individually. In such cases,

each medical device supplied individually must be licensed as a single medical device.

(ii) Family

- a. A medical device family is a collection of medical devices and each medical device,-
 - (i) is from same license holder;
 - (ii) is of same risk classification class;
 - (iii) has a common intended use;
 - (iv) has the same design and manufacturing process;
 - (v) has variations that are within the scope of the permissible variants.
- b. The characteristics of a medical device may be considered as permissible variant under clause (1), if-
 - (i) the physical design and material of construction of the medical device are the same or very similar;
 - (ii) the manufacturing processes, including sterilisation method, for the medical devices are the same or very similar;
 - (iii) the intended purpose of medical devices is the same; and
 - (iv) the risk profile of the medical device, taking into account the above factors, is the same.

Illustration:

- A. Condoms that differ in colour, size and texture but are manufactured from the same material and manufacturing process and share a common intended purpose can be licenced as a Family.
- B. Spherical contact lens with additional features of UV protection can be licenced as part of a Family, as this feature does not affect the basic design or manufacturing of the lens.
- C. Contact lens are available as toric lens and 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.

Illustration:

- A. A hip replacement system comprising of femoral and acetabular components can be licenced as system. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of component may vary.
- B. A glucose monitoring System comprising of a glucose meter, test strips, control solutions and linearity solutions can be licenced as a System.

(v) *In vitro* diagnostics cluster

An *in-vitro* diagnostics cluster comprises of a number of *in-vitro* diagnostics reagents or articles which are,-

- (i) from same license holder;
- (ii) of a common methodology;
- (iii) sold under single proprietary name; and
- (iv) compatible when used as a Test Kit.

(vi) Group

- a. A medical device Group is a collection of two or more medical devices, supplied in a single package by same license holder, which are,-
 - (i) sold under single proprietary Group name; and
 - (ii) a common intended purpose.
- b. The medical device in the Group may have different proprietary name and intended purpose and designed and sold by different license holder.
- c. The collection of medical devices in a Group may differ in the number and combination of products that comprises each Group, while maintaining the same proprietary Group name and Group's intended purpose.
- d. The medical device in a Group is supplied for use in another Group, such a medical device shall be included in the application of that other Group.

Illustration: A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package, can be licenced as a Group.

(iii) *In vitro* diagnostics Test Kit:

- a. An *in-vitro* diagnostics kit is a device that consists of reagents or articles which are,-
 - (i) from same license holder;
 - (ii) intended to be used in combination to complete a specific intended purpose;
 - (iii) sold under single proprietary Test Kit name; and
 - (iv) compatible when used as a Test Kit;
- b. An *in-vitro* diagnostics kit does not include the instruments, such as analysers, need to be perform the test.
- c. Individual reagents or articles can be supplied separately as replacement items for kit. If the reagents or articles in a Test Kit are supplied for use in more than one Test Kit, such reagents or articles shall be included in the application of the other Test Kits.

Illustration:

Human Immunodeficiency Virus (HIV) Enzyme Linked Immunosorbent Assay (ELISA) Test Kit may contain controls, calibrators, and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be licenced as Test Kit. These reagents and articles can be supplied separately as replacement items for that particular Test Kit.

(iv) System:

- a. The medical devices comprises system , that are-
 - (i) from same license holder;
 - (ii) Intended to be used in combination to complete a common intended purpose;
 - (iii) Compatible when used as system; and
 - (iv) sold under single proprietary system name;
- b. The constituent component in a system which is supplied for use in more than one System, such constituent components shall be included in the application for licence for each of other System.
- c. If the several system fulfil the conditions, as specified in clause (b), to be grouped as Family, they may be licenced as family.

Subject: **Issuance of Guidelines under the provisions of the Medical Devices
Rules 2017 on Grouping of medical devices and in vitro
diagnostics-reg**

To: Eswara Reddy <dci@nic.in>

Date: 03/13/18 04:01 PM

From: "Drug Regulation Section" <drugsdiv-mohfw@gov.in>

Issuance of Guidelines under the provisions of the... (62kB)

Sir,

Please find attached copy on the above subject and to request to take necessary action.

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With Warm Regards:

Drug Regulation Section,
D/o Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhawan, New Delhi.

[File NoX.11035/49/2018-DR]



(Debananda Sahoo)

Deputy Secretary to the Government of India



Government of India
Ministry of Health and Family Welfare
(Department of Health and Family Welfare)

New Delhi, March, 2018

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- b. The characteristics of a medical device may be considered as permissible variant under clause (1), if-
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- a. An *in-vitro* diagnostics kit is a device that consists of reagents or articles which are,-
 - (i) from same license holder;
 - (ii) intended to be used in combination to complete a specific intended purpose;
 - (iii) sold under single proprietary Test Kit name; and
 - (iv) compatible when used as a Test Kit;
- b. An *in-vitro* diagnostics kit does not include the instruments, such as analysers, need to be perform the test.
- c. Individual reagents or articles can be supplied separately as replacement items for kit. If the reagents or articles in a Test Kit are supplied for use in more than one Test Kit, such reagents or articles shall be included in the application of the other Test Kits.

Illustration:

Human Immunodeficiency Virus (HIV) Enzyme Linked Immunosorbent Assay (ELISA) Test Kit may contain controls, calibrators, and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be licenced as Test Kit. These reagents and articles can be supplied separately as replacement items for that particular Test Kit.

(iv) System:

- a. The medical devices comprises system , that are-
 - (i) from same license holder;
 - (ii) Intended to be used in combination to complete a common intended purpose;
 - (iii) Compatible when used as system; and
 - (iv) sold under single proprietary system name;
- b. The constituent component in a system which is supplied for use in more than one System, such constituent components shall be included in the application for licence for each of other System.
- c. If the several system fulfil the conditions, as specified in clause (b), to be grouped as Family, they may be licenced as family.

Illustration:

- A. A hip replacement system comprising of femoral and acetabular components can be licenced as system. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of component may vary.
- B. A glucose monitoring System comprising of a glucose meter, test strips, control solutions and linearity solutions can be licenced as a System.

(v) *In vitro* diagnostics cluster

An *in-vitro* diagnostics cluster comprises of a number of *in-vitro* diagnostics reagents or articles which are,-


- (i) from same license holder;
- (ii) of a common methodology;
- (iii) sold under single proprietary name; and
- (iv) compatible when used as a Test Kit.

(vi) Group

- a. A medical device Group is a collection of two or more medical devices, supplied in a single package by same license holder, which are,-
 - (i) sold under single proprietary Group name; and
 - (ii) a common intended purpose.
- b. The medical device in the Group may have different proprietary name and intended purpose and designed and sold by different license holder.
- c. The collection of medical devices in a Group may differ in the number and combination of products that comprises each Group, while maintaining the same proprietary Group name and Group's intended purpose.
- d. The medical device in a Group is supplied for use in another Group, such a medical device shall be included in the application of that other Group.

Illustration: A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package, can be licenced as a Group.

[File NoX.11035/49/2018-DR]



(Debananda Sahoo)

Deputy Secretary to the Government of India



Ministry of Health

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	<ol style="list-style-type: none">1) Sold as a distinct packaged entity.2) Does not meet criteria for family, System, or Group.	<ol style="list-style-type: none">1) Separate fee for each single device.2) Separate documentation for each single device.
2	Family	<ol style="list-style-type: none">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.	<ol style="list-style-type: none">1) Single fee for a family.2) Common DMF.
3	System	<ol style="list-style-type: none">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.	<ol style="list-style-type: none">1) If a system is proposed to be imported or manufactured for sale as Single Unit Pack only but not as individual components:<ol style="list-style-type: none">(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

			<p>manufactured for sale as Single Unit Pack or as individual component:</p> <p>(i) Separate fee for each of the components of the system.</p> <p>(ii) Separate documentation for each of the components of the system.</p>
4	Group	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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 (<i>endotracheal tube, tracheostomy tube</i>)	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 medical devices other than 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	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 1) If the a system is proposed to be imported or manufactured for sale as Single Unit Pack only but not as individual components: <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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.	-
