

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (186)

Date: **13 SEP 2021**

Subject: Classification of Medical Device pertaining to Personal Protective Equipment under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.



(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

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Directorate General of Health Services
Central Drugs Standard Control Organisation
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Classification of Medical Devices Pertaining to Personal Protective Equipment

S. No.	Medical Device Name	Intended Use	Risk Class
1	Garment, Protective for Incontinence	Intended to protect an incontinent patient's garment from the patient's excreta.	A
2	Biosanitizer for Medical devices	Intended for surface disinfection of medical devices, non porous hard-surfaces, medical-equipment, units, as well as in-depth cleaning of small surfaces.	B
3	Face shield	Intended to protect the wearer's entire face (or part of it) from hazards such as chemical splashes (in laboratories or in industry), or potentially infectious materials (in medical and laboratory environments).	A
4	Latex surgical glove	Natural rubber based glove intended to protect the patient and wearer from cross infection when used in medical or dental surgery.	B
5	Non-latex surgical glove	Synthetic material glove intended to protect the patient and wearer from cross infection when used in medical or dental surgery.	B
6	Radiation protection gloves	A personal protection device that completely protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.	A
7	Partial hand radiation protector	A flat pad with straps or partial gloves that protect part of hands and fingers from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.	A
8	Radiation protection apron	A standard length or half-length apron to protect the patient, the operator, and other personnel from radiation exposure during a medical or dental procedure. Some have a fixed or removable collar to protect the neck and thyroid.	A
9	Radiation protection mitten	A personal protection device that protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. The mittens are also called mitts, and protect the thumb and other fingers individually or together.	A

10	Radiation protection goggles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment.	A
11	Radiation face protector	A transparent or opaque personal protection device that protects the face and eyes of medical personnel and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.	A
12	Operator radiation protection spectacles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment. The device comes in non-correction (non-prescription) glasses and visual acuity correction (prescription) glasses.	A
13	Gonadal radiation protector	A personal protection device that attenuates unnecessary radiation exposure in diagnostic, medical or dental procedures, and shields the gonad of the patient and the operator.	A
14	Radiation protection blanket	A personal protection device that protects specific body parts of the patient, operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.	A
15	Radiation protection collar	A personal protection device that protects the neck or thyroid of the patient, the operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.	A
16	Radiation protection cap	A personal protection device that protects the head of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical procedures for diagnosis and treatment.	A
17	Mobile radiation protection barrier	A stand-alone, movable barrier that protects the operator etc. from unnecessary exposure to radiation used for medical diagnosis, treatment and dental procedures.	A
18	Non-latex medical examination glove	Gloves made of synthetic materials, and used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.	A
19	Latex medical examination glove	Natural rubber gloves used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.	A
20	chemotherapy spill clean-up kit	Designed to safely clean and dispose of Chemotherapy drug spills.	A
21	Medical/Cadaver Body Bags	Intended for transporting a human corpse without any spread of biohazard/infectious agent.	A

22	Surgical gown (Sterile)	A sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	B
23	Surgical gown (Non-Sterile)	A non-sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	A
24	Isolation Gown) (Sterile)	A sterile garment made of natural and/or synthetic materials intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect the themselves from a contagious agent which has infected the patient.	B
25	Isolation Gown (Non-Sterile)	A non-sterile garment made of natural and/or synthetic materials intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect the themselves from a contagious agent which has infected the patient.	A
26	Patient Gown	A garment made of natural and/or synthetic materials (e.g., paper, cloth, plastic) intended to be worn by patients in a clinical setting (e.g., during hospitalization, during examination in a doctor's office). A patient gown is usually short-sleeved and may be closed by ties at the back/side of the garment.	A
27	Professional Examination Gown	A garment made of natural and/or synthetic materials intended to be worn by healthcare providers, sometimes over scrub suits, while examining patients. It can be fluid resistant or impervious to fluid. An examination gown is used during patient examination procedures to protect both the patient and staff from the transfer of contaminants such as microorganisms or body fluids.	A
28	Personal Protective Equipment	PPE kit used to acts as a barrier between infectious materials such as viral and bacterial contaminants and skin, mouth, nose, or eyes. It refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.	B
29	Surgical Helmet	Intended to protect healthcare workers from contaminants & debris on head.	A
30	Surgical Cap	Intended to protect face of patient & the operating room personnel from the transfer of micro-organisms, body fluids & particulate material.	A
31	Operating Room Shoes Cover	Intended to be worn by operating room personnel during surgical procedures to protect foot of both the surgical patient & the operating room personnel from transfer of micro-organisms, body fluids, and particulate material.	A

32	Surgical Drape & Drape Accessories	A surgical drape & drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial & other contamination.	B
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