DECISION JAWATANKUASA TEKNIKAL PENGKELASAN DAN PENDAFTARAN (JKTPP) YEAR 2025

List of products (Medical device risk classification)

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
1.	Servox Digital XL Speech Aid	The SERVOX® digital XL speech aid offers patients, who have lost their voice due to injury, illness or surgical removal of the larynx, the opportunity to quickly regain the ability to communicate. The SERVOX® digital XL can also be used by patients who are temporarily voiceless due to a tracheotomy, who have to protect their vocal folds due to illness or who are connected to a respirator. Even patients who are comfortable using the oesophageal voice can use the SERVOX® digital XL in a variety of scenarios, e.g. for making phone calls, at business meetings, when they are tired, sick or very stressed, in an emergency, or in settings where speaking in a loud voice is essential.	The SERVOX® digital XL speech aid offers patients, who have lost their voice due to injury, illness or surgical removal of the larynx, the opportunity to quickly regain the ability to communicate. The SERVOX® digital XL can also be used by patients who are temporarily voiceless due to a tracheotomy, who have to protect their vocal folds due to illness or who are connected to a respirator. Even patients who are comfortable using the oesophageal voice can use the SERVOX® digital XL in a variety of scenarios, e.g. for making phone calls, at business meetings, when they are tired, sick or very stressed, in an emergency, or in settings where speaking in a loud voice is essential.	Class B, Rule 9(i)	All active therapeutic devices intended to administer or exchange energy are classified as class B, Rule 9(i). Based on the IFU, the working principle of this medical device is to send vibrations down the oral cavity so that voice can be produced. The medical device barely falls under Rule 9 (i) for the transfer of sound energy.

2.	BLOOD CULTURE SYSTEM SERIES	It is intended to grow and detect microorganisms (bacteria and fungi) from human blood or sterile body fluids.	The Blood Culture System is a qualitative automated instrument for in vitro diagnostic use in clinical laboratories. It is intended to grow and detect microorganisms (bacteria and fungi) from human blood or sterile body fluids.	Class B, Rule 6	A blood culture system — comprising both the analyser and the blood culture bottles — is not considered a general laboratory instrument or medium under Rule 5. While general culture media and general analysers used for non-critical specimens may fall under Class A, Rule 5, blood culture bottles are not general-purpose media. They are specialised reagents intended for direct inoculation with patient blood and designed to work with the analyser for the initial detection of pathogenic microorganisms in a sterile body fluid. As stated in the brochure provided, under Blood Culture Bottles have provided:

					Blood culture is one of the most crucial examinations in clinical microbiology laboratories, serving as the gold standard for diagnosing bloodstream infections and bacteraemia. The results of blood cultures hold significant clinical significance for the diagnosis, treatment and prognosis of infectious diseases. In the report provided also includes microbial species name as well.

3.	FLAYYA POST TREATMENT	FLAVYA POST TREATMENT OCCLUSIVE FACE MASK is a medical device composed of biocellulose film and hyaluronic acid. Medical device, due to gravitational compression and water-binding properties, creates an occlusive barrier layer. The product is not sterile. The device does not contain any medical purpose. It is also not a measuring device, nor does it receive or provide data from patients.	The medical device is intended for application to facial skin after aesthetic medicine procedures, biocellulose combined with hyaluronic acid creates an occlusive layer to reduce bruising, swelling and redness. It is intended for all skin types. Patients after treatments performed on facial skin, soothing and cooling of damaged and irritated skin after aesthetic medicine treatment. Apply the mask to cleansed face and remove mask after 15 minutes. Single use only.	Class A, Rule 4	

List of products (Medical device or Non-medical device)

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
1.	SIDE RAIL	To reduce the risk of falls form bed.	Accessories for hospital bed made from mild steel framework.	Medical Devices	Medical devices if the product is intended for accessories of hospital bed.

**The product intended use and description are based on the information submitted in the Medical Device Registration application in MeDC@St system*