

Recommendations of the SEC (Cardiovascular) held on 08.01.2025 at CDSCO (HQ), New Delhi:

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---------------------------------|---|--|--|
| Medical Devices Division | | | |
| 1. | CI/MD/2024/114137 Atrial Septal Defect BioResorbableOccluder (Brand Name: Floret™ BRO) | M/s. Meril Life Sciences Private Limited | <p>The proposal of the Clinical Investigation study having protocol number MLS/FLORET-1, Version:1.0.0 dated 07-Aug-2023 for the conduct of clinical investigation on the applied device Atrial Septal Defect BioResorbableOccluder, in the country on Indian population, was discussed before the expert committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of said clinical study with the following conditions:</p> <ol style="list-style-type: none"> 1. In the inclusion criteria, the applicant shall include male and female population of the age group between 08 to 40 years only. Also, the ASD/Fontan Fenestration closure with defect size (Diameter of Waist of Occluder) shall be revised to the range of '06-24 mm', instead of '06-40 mm'. 2. All patients should undergo Transesophageal echocardiogram (TEE) procedure. 3. All Principal investigators should possess DM Cardiology Degree. <p>Accordingly, the firm may submit revised inclusion criteria before initiation of the study.</p> |