

Recommendations of the SEC (Cardiovascular) made in its 03rd/25 meeting held on 06.02.25. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	MFG/MD/2024/1324 52 Mitral Heart Valve (Brand Name: TRIA)	M/s. Dolphin Life Science India LLP	<p>The proposal of the firm along with the Clinical Study data generated on the Indian population was deliberated before the expert committee.</p> <p>After detailed deliberation, the expert committee asked for following information, for further deliberation:</p> <ol style="list-style-type: none"> 1) Detailed causality assessment report on the Serious adverse events reported, especially about each mortality in detail. 2) The explanation on the non-adherence to the Clinical study protocol (about the use of anticoagulants beyond 3 months) as approved by Central Licensing Authority.