

Recommendations of the SEC (Cardiovascular) made in its 07th/25 meeting held on 21.05.2025 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 detailed clinical study data generated on the applied device in Indian population was further deliberated before the expert committee.</p> <p>After detailed deliberation, the expert committee recommended for grant of permission to manufacture the said device in the country, with the condition that, after the launch of the product in the market, the firm shall submit Post Marketing Clinical Follow-up data on initial 100 patients who will undergo implantation of the device, periodically for the period of next 04 years along with follow-up data of the patients already enrolled in the clinical investigation study (Protocol no. CP-004-Revision-F dated: 27/06/2022) in the country, to have long term safety and performance data of the device.</p>