

Recommendations of the SEC (Cardiovascular) made in its 05th/26 meeting held on 18.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	IMP/MD/2025/145135 Cool line Intravascular Heat Exchange Catheter Kit (ZOLL), ICY Intravascular Heat Exchange Catheter Kit (ZOLL), Quattro Intravascular Heat Exchange Catheter Kit (ZOLL), Solex 7 Intravascular Heat Exchange Catheter Kit (ZOLL)	M/s. ZOLL MEDICAL INDIA PRIVATE LIMITED	The proposal for grant of permission to import investigational medical device viz. Intravascular Heat Exchange Catheter Kit, was redeliberated in the presence of Critical care specialists and anesthesiologists. After detailed deliberation, the experts recommended for the permission to import the investigational medical device on the condition that indications for use and warning for each variant of the said device should be in-line with that approved by the National Regulatory Authority of Country of Origin.
Biological Division			
2.	BIO/CT04/FF/2025/53 256 Alteplase 2mg	M/s. Reliance Life Sciences Pvt. Ltd.	The firm did not attend the meeting.