

**Recommendations of the SEC (Ophthalmology) made in its 09<sup>th</sup>/25 meeting held on 17.09.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Medical Devices Division</b>			
1.	CI/MD/2024/130793  Intraocular pressure monitoring device for Tonometry	M/s. OKO ICARE SOLUTIONS PRIVATE LIMITED	<p>The firm has requested for permission for conduct of Clinical investigation on the device.</p> <p>The firm has presented their revised Clinical study protocol, vide number OISN/ELTM-01/PIVOTAL-P/067, version 1.1 dated 19.07.2025 as per the recommendations of the SEC (Ophthalmology) meeting held on 24.06.2025.</p> <p>After detailed deliberation, the committee recommended for conduct of the said Clinical investigation on the Indian population to generate the clinical safety data.</p>