



24 April 2026

Webinar on breakthrough medical devices

Agenda – 24 April 2026 (15:00 – 17:00 CEST), [registration page](#)

Item	Agenda	Mins
1.	Welcome	5'
PART I Guidance on breakthrough devices - MDCG 2025-9: General considerations and regulatory context		
2.	Overview of breakthrough devices guidance	20'
3.	European Commission's perspective and expectations	10'
4.	Industry's perspectives on practical implications	15'
PART II Guidance on Breakthrough Devices - MDCG 2025-9: Procedural considerations		
6.	Role of expert panels in the breakthrough devices framework	30'
	<ul style="list-style-type: none">Assessing medical device innovation: past and future contributions of expert panelsConceptual approach and request management	15' 15'
7.	Notified body's activities and responsibilities	15'
PART III		
8.	Q&A	20'
9.	Conclusions and next steps	5'

