

New EU requirements for MUDI Updates MSWG

Project Lead: Greg Rowe

OGSM
Report Date: October 2025
Expected project close date Q2 2026

Business purpose

- This group will develop the appropriate solution. The European (EU) Commission submitted a work request to develop the creation of "Master UDI-DI" for spectacle frames, spectacle lenses and ready-to-wear reading spectacles as part of the UDI requirements based on the European Medical Device Regulation (MDR).

Key issues and risks

- EU COM delegated act has not been finalised. The team is moving forward with the current understanding of the potential language in the delegated act which could impact the draft GSCN.

Accomplishments this period

- Team completed the RCAD (Regulatory Clarifications Assessment Document)
- Team approved the BRAD and motioned it to Community Review
 - ComRev ends 13 October

Upcoming period activities

- Complete ComRev Resolution
- Motion BRAD to eBallot



New EU requirements for medical devices identification MSWG

Overall Status

#	Standard /guideline Milestones	Due Date	Notes	#	Collateral milestones	Due date	Notes
1	Master UDI-DI GSCN	Q2 2026		1	TBD	TBD	
2							
3							
4							
5							

Stakeholders

Project Scope, Resources and Timeline Change Management

Sponsor	Robert Beideman			Kick-off call May 2025					
SDL	Greg Rowe								
CE/Sol Liaison									
SME	Neil Piper								
AG Liaison	Shekhar Nambi – J&J								
Chairs	Lionel Tussau – Bayard Consulting, Sylvia Reingardt – GS1 Germany, Jeremie Consoln								
New risks identified	Yes/no	Change request included	Yes/no	Legend	Complete	Not Started	On target	Risk of being late	Change needed (not recoverable)