New EU requirements for MUDI Updates MSWG

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

Project Lead: Greg Rowe

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 is following pervious phase and developing an RCAD (Regulatory Clarifications Assessment Document)
- Team reviewed and resolved half of the comments received for the RCAD

Upcoming period activities

- Complete resolution of comments to RCAD
- Begin outlining the BRAD based on RCAD

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

Sponsor	Robert Beideman
SDL	Greg Rowe
CE/Sol Liaison	
SME	Neil Piper
AG Liaison	Shekhar Nambi – J&J
Chairs	Lionel Tussau – Bayard Consulting, Sylvia Reiingardt – GS1 Germany, Jeremie Consoln

Project Scope, Resources and Timeline Change Management

Kick-off call May 2025

New risks identified	Yes/no	Change request included	Yes/no	Legend	Complete	Not Started	On target	Risk of being late	Change needed (not recoverable)