New EU requirements for medical devices identification MSWG

Project Lead: Greg Rowe

OGSM
Report Date: November 2023
Expected project close date Q1 2024

Business purpose

- This group will develop the appropriate solution required by the European Commission to develop a Master UDI-DI for implementation of a new level of identification of eyewear products and other devices 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

- Completed BRAD #3 ComRev comment resolution and passed eBallot
- Team agreed to new timeline of completion date of Q1 2024
- Team working on Design Assumption phase
- Currently conducting a Poll to choose one MUDI Option for Made to Order contacts

Upcoming period activities

- Review MUDI Option poll results and complete Design Assumption phase

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Overall Status

#	Standard/guideline Milestones	Due Date	Notes	#	Collateral milestones	Due date	Notes
1	Master UDI-DI GSCN	Q1 2024		1	TBD	TBD	
2							
3							
4							
5							

Stakeholders

Sponsor	Marianne Timmons
SDL	Greg Rowe
CE/Sol Liaison	Geraldine Lissalde Bonnet
SME	Neil Piper
AG Liaison	John Terwilliger - Abbott
Chairs	Scott Durland – J&J, Lionel Tussau – atrify, Sylvia Reiingardt – GS1 Germany

Project Scope, Resources and Timeline Change Management

- IESC approval date 9/21

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