

New EU requirements for medical devices identification MSWG

Project Lead: Greg Rowe

Report Date: March 2024
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

- With numerous comments during the community review period, there is a chance that all comments may not be resolved until the end of March and eBallot may not happen until April.

Accomplishments this period

- GSCN was motioned to public community review, ending 13 February
- GO Team in process of reviewing and developing proposed resolutions

Upcoming period activities

- Begin comment resolution phase
- Three consecutive calls are scheduled to complete the comments
- Motion 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	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 - Bayard, Sylvia Reingardt - GS1 Germany

Project Scope, Resources and Timeline Change Management

- IESC approval date 9/21
- 29 Feb - With numerous comments during the community review period, there is a chance that all comments may not be resolved until the end of March and eBallot may not happen until April.
- 29 Feb - to help progress this work, weekly calls have been set up from 07 March to 04 April

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