New EU requirements for medical devices identification MSWG

Project Lead: Greg Rowe

Report Date: May 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

- None at this time

Accomplishments this period

- GSCN was ratified on 03 May

Upcoming period activities

- The MSWG will remain open/dormant in case there is further need to extend the scope of the Master UDI-DI to other type of devices, and/or need to further clarify the EU COM guidelines on important points for global implementation of our standard.

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Overall Status

#	Standard/guideline Milestones	Due Date	Notes	#	Collateral milestones	Due date	Notes
1	Master UDI-DI GSCN	Q1 2024	GSCN was ratified on 03 May.	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 Reiingardt – 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)