New EU requirements for medical devices identification MSWG

Project Lead: Greg Rowe

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).

Accomplishments this period

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

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.

Upcoming period activities

• Begin comment resolution phase
• Three consecutive calls are scheduled to complete the comments
• Motion to eBallot

Report Date: March 2024
Expected project close date Q1 2024
**New EU requirements for medical devices identification MSWG**

### Overall Status

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<tr>
<th>#</th>
<th>Standard/guideline Milestones</th>
<th>Due Date</th>
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### 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

### Change Management

- New risks identified
- Change request included

<table>
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<th>Risk of being late</th>
<th>Change needed (not recoverable)</th>
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