## 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).

### Key issues and risks

- None at this time

### Accomplishments this period

- Team conducted three consecutive calls to complete the community review comments
- Motioned GSCN to eBallot on 28 March call
- SMEs will update GSCN. Once complete, eBallot will start week of 08 April
- It was requested on the 28 March to keep the MSWG open to review future updates

### Upcoming period activities

- Ratification
- GS1 GO SMEs will review re-arranging sections of the HC Application Standards, per two comments in the ComRev.
## New EU requirements for medical devices identification MSWG

### Overall Status

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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**: Yes/no
- **Change request included**: Yes/no

### Legend

- Complete
- Not Started
- On target
- Risk of being late
- Change needed (not recoverable)