



Workshop on Unique Device Identification (UDI) for contact lenses

Navigating EU Medical Device Regulation (MDR) requirements for assignment, labeling, registration and vigilance reporting of Master UDI

Thursday 28 November 2024

Regus meeting center & Teams visioconference

13:30 - 13:45 Welcome and introduction | Laure-Anne Martinet, EuromContact - Moderator

Part I : Assignment and labeling rules of UDI for contact lenses

13:45-14:20 UDI assignment for standard contact lenses | Nicky Soubry, PureCon
*Assignment rules for Basic UDI-DI, Master UDI-DI and UDI-PI, labeling rules
Q&A with participants*

14:20-15:00 UDI assignment for made-to-order contact lenses | Nicky Soubry, PureCon
*Assignment rules for Basic UDI-DI, Master UDI-DI and UDI-PI, labeling rules
Q&A with participants*

Coffee break

15:15-15:45 Case study on GS1 standards for Master UDI | Géraldine Lissalde-Bonnet, GS1
*Presentation of GS1 standards for standard and made-to-order contact lenses UDI
Q&A with participants*

Part II : Registration of contact lenses in Eudamed

15:45-16:30 Registration of Master UDI in the Device/UDI module of Eudamed | Pierre-François Ryelandt, European Commission
*Presentation of the Eudamed database and registration obligations for contact lenses
Q&A with participants*

16:30-17:00 Practical case in Eudamed Playground | Scott Durland, Chair of EuromContact UDI WG

Part III : Vigilance reporting

17:00- 17:20 Vigilance reporting requirements for MDR contact lenses and for legacy contact lenses | Nicky Soubry, PureCon
Q&A with participants

17:20-17:30 Wrap-up and overview of the timeline on the implementation of Master UDI | Laure-Anne Martinet, EuromContact – Moderator