EUROMCONTACT
THE EUROPEAN ASSOCIATION OF THE
CONTACT LENS AND LENS CARE INDUSTRY

Getting ready for EUDAMED and Swissdamed compliance

Device registration for contact lenses and lens care products

13 April 2026 | 14:00 - 17:00

Online workshop

Welcome & program overview

Session 1 : EUDAMED: from regulatory framework to practical implementation

14:05 – 14:50 | Introduction : Regulatory framework of EUDAMED

Speakers : Silvia OSTUNI, Legal and Policy Officer, European Commission & Pierre-François RYELANDT, Policy Officer, European Commission

- **Overview of the objectives, legal basis and obligations related to EUDAMED**
- **Devices module : what must be registered, by whom, and by when?**
  - ✓ Understanding legacy, old, and Regulation devices
  - ✓ Timelines for registration obligations
- **Sources of information and onboarding activities**
- **Q&A session**

14:50 – 15:10| Registration of contact lenses and lens care products in Eudamed UDI / devices module - Theory

Speaker : Nicky SOUBRY, PureCon

- **Reminder of the key concepts**
  - ✓ Device categorisation
  - ✓ Device identifiers in EUDAMED

- ✓ Registration process and specific rules
- ✓ Data exchange options
  - User Interface (manual input of data through the application)
  - XML bulk upload
  - Data Exchange (DTX) Machine-to-Machine (M2M) system

- **Prerequisites for device registration in EUDAMED**
  - ✓ EU login account
  - ✓ Actor registration in EUDAMED
  - ✓ Local Actor Administrator (LAA) and Local User Administrator (LUA) profiles
  - ✓ (M)UDI-DI assignment
- **General flow of registration in the UDI/Devices module**

15:10 – 15:30| Addressing common questions and practical challenges in EUDAMED registration

Speaker : Nicky SOUBRY, PureCon

- **Choosing the most appropriate data submission method:** Advantages and limitations of each option (User interface, XML bulk upload, M2M), depending on catalogue profile
- **Data requirements and level of granularity in device registration fields:** Industry good practices and practical recommendations
- **Q&A session**

***** Coffee break *****

15:40 – 16:40 | Registering contact lenses and lens care products – Practical demonstrations

Speaker : Nicky SOUBRY, PureCon

- **Legacy device registration (for UDI-DI only)**
  - ✓ Overview of the 6-step process
  - ✓ Live demonstrations for lens care product/ IOL
    - via webform
    - via bulk upload
- **Q&A session**
- **Regulation device registration**
  - ✓ Live demonstrations using Master UDI-DI (standard contact lenses / MTO contact lenses) and UDI-DI (lens care product/ IOL)
    - via webform
    - via bulk upload
  - ✓ Demonstration: UDI-DI registration to an existing Basic UDI-DI already registered

- ✓ Demonstration: linking a legacy device to a regulation device
- **Q&A session**
- **Device management in EUDAMED**
  - ✓ Demonstration : Updating Basic UDI-DI / EUDAMED DI
  - ✓ Demonstration : View Basic UDI-DI / EUDAMED DI historical versions
- **Q&A session**

Session 2 : Swissdamed, regulatory framework and device registration requirements in Switzerland

16:40 – 17:00 | Swissdamed: overview and requirements in Switzerland

Speaker : Susanne WYDENKELLER HINDER, Head of Division Medical Devices Operations & Development, Swissmedic, Swiss Agency for Therapeutic Products

- **Timeline for implementation and key device registration requirements in Switzerland**
  - ✓ Swissdamed background
  - ✓ Similarities and differences between Swissdamed and EUDAMED
  - ✓ Timelines
- **Q&A session**

Closing remarks