Meeting Overview			
Meeting Title	T819 DITA Eyewear Importer Obligations – Client connect		
Meeting Date	17th June 2026	***Meeting Location***	MS Teams
Objective & Participants			
Objectives of the meeting	• Plan approach and initial activities		
Participants	**Trinzo:** Colm O'Rourke Mark Kelleher John-Paul Huges Jenny Gough	**Client:** Orla Skally	

Meeting Minutes	
QMS	Mark gave an update that he has drafted a QMS Manual – Emphasis that the QMS procedures need to align with existing business processed to ensure usability and sustainability. This will serve as the building block for developing the required compliance documents. Jacqui has shared this to Orla for review.
Process Overview	Orla gave an overview of the movement of goods. **Goods Movement** • Purchased by DITA Inc directly from Japanese suppliers • Shipped – First point of entry into EU is in Netherlands – Fiscal clearance House by 3rd Party (goods help temporarily at the airport while cleared) • Goods released and transported to Ireland • Final storage location is Warehouse on site in Park West (DEEL HQ) • Whse process primarily manual – scanners used for picking. **Packaging** • Products stored in original packaging (Poly bag + White box) • Items already barcoded at the factory • Some checks performed (nothing comprehensive) **Customer Orders** • Wholesale Opticians place orders via B2B platform / Sales Rep / Customer Service team • Orders entered in system (NetSuite) • Reviewed and approved by Customer Service **Order Picking** • Products are allocated to the sales order • Order moves to Whse Picking queue • Shipping label generated (order details + barcodes) • Box selected and labelled • Operators pick items using handheld barcode scanners (RF Smart)

	• Products located via bin-number storage system
	
	Packing
	• Products move to packing area
	• Units are:
	  ○ Removed from original packaging
	  ○ Repacked into DITA branded packaging
	• Additional inserts included (where applicable):
	  ○ Warranty booklet / manufacturer's information note
	Final step:
	• Outer shipping label applied (customer-facing label)
	
	Completed shipments:
	• Packed into shipping boxes
	• Invoice printed and included in shipment
	Distribution:
	• Courier: DHL
	• Dispatch timeline: Same day or next day
	• Delivery timeframe: Typically next day across Europe
	• Shipped directly to customer stores

UDI and Regulatory Data	Currently, UPC codes are used for barcoding Currently implementing NEW Lot Numbering – Transition to 2D data matrix US managing label design and format. Jenny outlined the UDI compliance to include the production identifiers. She also outlined the key dates for EUDAMED Registration of Devices. All new devices must be registered in EUDAMED now. Existing products need to be registered in EUDAMED by 28th November '26 deadline. Legal Manufacturer has overall responsibility to complete the registration of the devices. Importer and Authorised Rep have responsibility to verify the registration are complete. As MedEnvoy are acting as the EO for the Manufacturer (DITA Inc) – they should be completing the registrations. It is important for both Orla and Trinzo have oversight of the timelines for these registrations to ensure they are informed in view of any upcoming audit by the HPRA for Importer. As an FYI - Jenny confirmed she has also checked the US FDA D/B and found no products registered – recommendation DITA Inc need to complete the registration to ensure compliance.
DoC's	John-Paul noted the need to update the DoC's for sunglasses to include EUMDR and PPE on one rationale. Orla confirmed the updates are in progress. The team also looked for a list of all countries to which devices are shipped – impact on translation considerations for DoC's - Orla will share the list.

HPRA Fees	Orla outlined they had received an invoice from the HPRA for annual Fees and asked for advice on whether they should challenge and/or pay. She will forward to Jacqui/Com to review.

Next steps		
Actions	***Owner***	***Deadline***
Orla to review the QMS Manual from the team	Orla	24th March '26
Followup with Cody for a copy of the MedEnvoy project plan for manufacturer EO	Orla	17th June '26
Orla to share a copy of the new label with Jenny for review	Orla	24th March '26
Orla to share a list of all the languages for DoC's	Orla	24th March '26
Review the DoC's for sunglasses for MDR and PPE compliance	John-Paul	24th March '26
Review HPRA invoice fee	Jacqui	24th March '26