EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

COM (2025) 3484

COMMISSION DELEGATED REGULATION (EU) 2025/1920 of 12 June 2025 amending Regulation (EU) 2017/745 of the European Parliament and of the Council, as regards the assignment of Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

Submitted by Department of Health and Social Care, 24 February 2026

SUBJECT MATTER

Background: Overview of the Unique Device Identifiers System under current EU regulations

1. Regulation (EU) 2017/745 (the 'EU Medical Devices Regulation' (EU MDR)) of the European Parliament and of the Council sets the regulatory framework for medical devices for EU Member States. Under the terms of the Windsor Framework, this regulation has applied directly in Northern Ireland (NI) since 26 May 2021, to facilitate NI's unique dual access to both the UK internal market and EU single market.

2. The EU MDR requires each medical device to have its own Unique Device Identification (UDI), which consists of a UDI Device Identifier (UDI-DI) and a UDI Production Identifier (UDI-PI). The UDI system was introduced to enable unambiguous identification and facilitate traceability of medical devices within the supply chain and when in use, by providing a single, standardised identifier for each medical device product to support effective post-market safety activities by both health authorities and manufacturers.

3. The UDI-DI is a fixed numeric or alphanumeric code specific to a manufacturer and a version or model of a medical device. The UDI-DI format follows internationally accepted device identification and coding standards set out by accredited issuing entities.

4. Manufacturers supplying to the EU's single market and/or NI are required to assign a UDI-DI to each medical device, place this UDI-DI on the label of the device, and register the UDI-DI to the European database on medical devices (Eudamed). This registration requirement will become mandatory on 28 May 2026 when the UDI/Device module of Eudamed is declared 'live'.

New Delegated Regulation COM (2025) 3484

5. According to the current rules of the UDI system, a UDI-DI must be assigned to each variant of a device and be registered on Eudamed from May 2026. Spectacle frames,

spectacle lenses and ready-to-wear reading spectacles are available in many variants due to the high number of designs (clinical and non-clinical) and construction parameters that characterise them.

6. According to the Explanatory Memorandum to Commission Delegated Regulation (EU) 2025/3484 and Medical Device Coordination Group (MDCG) Position Paper 2025-7, the requirement to enter a large number of UDI-DI entries into Eudamed for similar variants of spectacle frames, spectacle lenses and ready-to-wear reading spectacles products places a significant burden on manufacturers, distributors, and the Eudamed system. This burden is considered disproportionate to the low-medium safety risk profile of these products.

7. To resolve this issue and reduce the burden on businesses, on 12 June 2025, the European Commission adopted Delegated Regulation (EU) 2025/3484, pursuant to Article 27 (10) point (b) of the MDR, amending Part C of Annex VI of Regulation (EU) 2017/745, that provides for the assignment of one Master UDI-DI to similar variants of spectacle frames, spectacle lenses or ready-to-wear reading spectacles products, instead of a different UDI-DI to each variant.

8. The Master UDI-DI requirement will apply from September 2028 for spectacle frames, spectacle lenses and ready-to-wear reading spectacles products, three years from the date of entry into force of the Delegated Regulation. Since the mandatory use of the UDI Device registration module in Eudamed will apply from 28 May 2026, there will be a period between 28 May 2026 and Q3 2028 where labelling and registration of Master UDI-DIs onto Eudamed is not required, but the registration of individual UDI-DIs is.

9. A similar approach to the Master UDI-DI has been recently adopted for contact lenses via Commission Delegated Regulation (EU) 2023/2197, and Commission Delegated Regulation (EU) 2025/2258, with arrangements for contact lenses coming into effect from 9 November 2026.

SCRUTINY HISTORY

10. There has been no relevant scrutiny history of similar or relevant EU proposals previously subject to scrutiny. This is a new subject for the committee to scrutinise.

MINISTERIAL RESPONSIBILITY

11. Minister Zubir Ahmed

    Parliamentary Under-Secretary of State for Health Innovation and Safety

    Department of Health and Social Care

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

12. The regulation of medical devices is a reserved matter under the devolution settlements. Under the terms of the Windsor Framework, the EU legislation that applies in NI is listed

in Annex 2 to the Framework and includes the MDR. By virtue of Section 7A of the European Union (Withdrawal) Act 2018, the MDR applies directly in NI.

13. The MHRA continues to actively engage with the NI Department of Health and Devolved Governments in its work to develop the future regulatory framework for medical devices in the UK.

LEGAL AND PROCEDURAL ISSUES

14. **Application under the Windsor Framework**: Delegated Regulation (EU) 2025/3484 amending Regulation (EU) 2017/745 of the European Parliament and of the Council applies to NI under the terms of Article 13(3) of the Windsor Framework. Regulation (EU) 2017/745 is listed in Annex 2 of the Framework.

15. **EU Legal Base**: The Delegated Regulation is based on Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union (TFEU).

16. **Voting Procedure**: This legislation is being adopted via the ordinary legislative procedure. Therefore, the Council of the European Union will vote by qualified majority.

17. **Timetable for adoption and implementation:** The legislation was adopted by the European Commission on 12 June 2025. The Master UDI-DI requirement will apply from September 2028 for spectacle frames, spectacle lenses and ready-to-wear reading spectacles products, three years from the date of entry into force of the Delegated Regulation.

POLICY AND LEGAL IMPLICATIONS

Regulatory Regime in Great Britain of the UDI System

18. The UDI system is currently optional for medical devices that are placed on the market or put into service in Great Britain (GB). During registration of devices on the current Device Online Registration System (DORS), the manufacturer, or UK Responsible Person (UK RP) may voluntarily register the UDI for devices. The MHRA intends to make the assignment and registration of UDI to medical devices mandatory via the addition of this requirement to the UK Medical Devices Regulations 2002, using secondary legislation, which the MHRA intends to lay in Parliament during 2026. This legislation, therefore, will closely mirror the requirements of the EU MDR for the UDI system.

19. The intention of the UDI policy is to strengthen the ability to trace and identify medical devices in the supply chain and used by patients, therefore providing enhanced safety monitoring of devices on the market. The core elements of the UDI system for both GB and the EU will follow internationally harmonised standards to ensure consistent global implementation. This alignment is essential to realising the benefits of the UDI concept in the global medical device market.

20. The new GB regulations will require manufacturers to assign a UDI-DI to medical devices before placing or putting them into service on the GB market. Reusable medical devices will also need to bear a UDI carrier (a barcode or QR code) that is permanent and readable after each process of the device itself. The manufacturer, or the UKRP, must register and keep the UDI-DI information up-to-date on the DORS database. Healthcare professionals and/or healthcare institutions will be required to record the UDI for implantable medical devices linked to the patient they have been implanted into.

Overview of the UK spectacles and spectacle lens market

21. Spectacles are divided into three categories: ready-to-wear, frames, and lenses. MHRA registration data indicates that there are no NI-based manufacturers of spectacle frames and spectacle lenses, and two NI-based SME manufacturers of ready-to-wear reading spectacles, supplying both NI and GB.

22. **Spectacle frames**: The majority of spectacle frames supplied to both NI and GB are supplied by EU-based manufacturers (i.e. 65% of registered devices on the market). There is strong production of spectacle frames in the EU, and the major EU players also have strong export businesses (e.g. EssilorLuxottica also has the largest market share in the US spectacles market). Approximately 24% of registered spectacle frames on the GB and NI markets come from GB-based manufacturers, but most of those are also available for export to the EU market or in any case meet EU requirements, as over 99% of registered spectacle frames from GB are listed as compliant with EU regulations (CE-marked devices).

23. **Ready-to-wear**: The majority of ready-to-wear spectacles supplied to both NI and GB are supplied by GB-based manufacturers (i.e. 60% of registered devices on the market). There are 431 manufacturers of ready-to-wear spectacles in GB, with Specsavers being the largest provider with 40% market share and with small local players being a significant portion of the market. While only 15 EU-based manufacturers are registered with MHRA, they supply 36% of ready-to-wear spectacles products on the GB market. Over 95% of registered ready-to-wear spectacles in the UK are listed as CE-marked devices.

24. **Spectacle lenses:** Similarly, the majority of spectacle lenses supplied to both NI and GB are supplied by GB-based manufacturers (i.e. 74% of registered devices on the market). The number of manufacturers of spectacle lenses is significantly smaller, with 51 GB-based businesses and 17 EU-based manufacturers. Over 92% of registered spectacle lenses in the UK are listed as CE-marked devices.

Implications for the UK

25. **For industry**: Manufacturers and suppliers of spectacle frames, spectacle lenses and ready-to-wear reading spectacles to the EU or NI will need to introduce the Master UDI-DI into their processes and systems. There is anticipated to be an initial financial burden for adapting internal processes and equipment for assigning the new Master UDI-DI and amending the UDI labels on device packaging (e.g., printers, scanners for UDI carriers).

26. For manufacturers supplying to both NI and GB, there will be ongoing administrative burdens of assigning, labelling on the device packaging, and registering a Master UDI-DI for the EU and NI markets, and a UDI-DI for the GB and rest-of-the-world markets. As the vast majority of spectacle products supplied to the GB and NI market are compliant with EU requirements (as they are supplied by EU-based businesses or by GB-businesses that also export to the EU), disruption to supply is unlikely. This is evidenced by the fact that over 99% of registered spectacle frames, 95% of ready-to-wear, and 92% of spectacle lenses in the UK are CE marked devices. Therefore, since the main providers of these products supply to both the EU and NI, and GB and rest-of-the-world market, it is unlikely that supply to either NI or GB will be affected due to businesses being unwilling to comply with the new Master UDI-DI requirements.

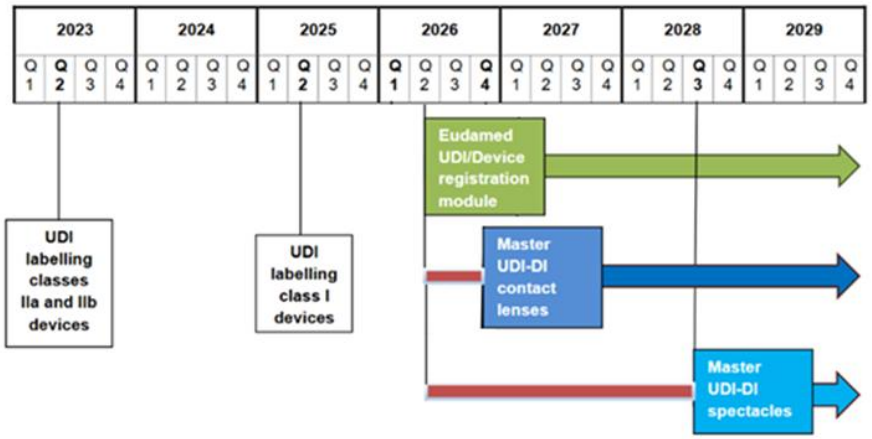
27. This is supported by feedback received from industry, in response to a call for comment issued in September 2025 to manufacturers of spectacle frames, spectacle lenses and ready-to-wear reading spectacles. We therefore do not expect any impacts on the availability of spectacles in NI or GB.

28. **For patients**: Supply disruption to either NI or GB is unlikely, as set out above**.** Therefore, there should be no noticeable impact on patients. Any supply disruptions are closely monitored in established processes by the Department.

29. **For Government**: The UK's registration system DORS will require manufacturers to register a UDI-DI for each medical device placed on the GB market. Therefore, CE-marked products carrying only the Master UDI-DI will need to also have a UDI-DI in order to register for the GB market. This will not apply to qualifying NI goods entering GB via NI, which will not have to have a UDI-DI. For CE marked products entering the GB market directly, which must have a UDI-DI in addition to the Master UDI, an optional field for a Master UDI-DI will also be available for registration on DORS of products complying with EU regulations.

30. CE-marked products will be able to enter the GB market either via unfettered access from NI as qualifying NI goods, or by continued acceptance of CE-marked medical devices on the GB market up until 30 June 2030 (noting that the Government has launched a consultation on the indefinite recognition of CE marking). As such, the MHRA will be able to continue surveillance of spectacle products carrying both or either a UDI-DI and Master UDI-DI across the UK market.

31. **Fragmented timelines**: The EU MDR Master UDI-DI requirements, and concomitant registration requirements, apply from September 2028. Until then, the existing (individual) UDI-DI requirements will continue to apply for spectacle products placed on the EU market and a registration requirement will be introduced from May 2026. The time spans from about 10 months for contact lenses to about 30 months for spectacle frames, spectacle lenses and ready-to-wear reading spectacles (see Fig. 1 below). While the different implementation timelines might make implementation slightly more complex, we expect this to be manageable.



In red the representation of the time lapses when the use of the UDI/Device registration module in Eudamed is mandatory but not the Master UDI-DI assignation yet:

- for contact lenses: from Q2 2026 to Q4 2026
- for spectacle frames, spectacle lenses and ready-to-wear reading spectacles: from Q2 2026 to Q3 2028

Fig 1. Master UDI-DI Implementation Timeline

32. The European Commission's intention with the Master UDI-DI is to streamline the Eudamed system and facilitate simplified monitoring and surveillance of highly individualised devices on the market. As this concept will be different from the existing globally harmonised system for identification and traceability of medical devices in the supply chain, the Government is reviewing and monitoring the implications of such an approach. Further analysis is needed, following implementation, to understand the financial implications involved for the full scope of this proposed legislation.

CONSULTATION

33. The MHRA and DHSC have close working relationships with the Northern Ireland Civil Service and regularly engage with the Northern Ireland Department of Health on medical device regulations. The MHRA and DHSC will continue to engage on the proposed amendments to ensure a smooth transition.

34. MHRA and DHSC launched a call for comments issued in September 2025, to manufacturers of spectacle frames, spectacle lenses and ready-to-wear reading spectacles. The themes of the comments have been incorporated into this Explanatory Memorandum.

FINANCIAL IMPLICATIONS

35. **For industry**: As mentioned above, there is anticipated to be an initial financial burden for adapting internal processes and equipment for assigning the new Master UDI-DI and amending the UDI labels on device packaging (e.g., printers and scanners for UDI carriers).

36. **For Government**: For MHRA, there will be an expenditure involved in adapting the IT systems for an optional field for Master UDI-DI within the UK's registration system, DORS.

MINISTERIAL NAME AND SIGNATURE

Minister Zubir Ahmed

Parliamentary Under-Secretary of State for Health Innovation and Safety

Department of Health and Social Care