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MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers

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Article 27 of Regulation (EU) 2017/745 on Medical Devices (MDR) introduces a Unique Device Identification (UDI), which among other functions aims to improve the identification of devices and enhance the effectiveness of post-market safety-related activities for devices. This position paper is intended to provide clarification on UDI assignment obligations for manufacturers of Spectacle lenses & Ready readers. It should be read in conjunction with the relevant provisions of Regulations (EU) 2017/745 (notably Chapter III and Annex VI) and related UDI guidance documents.

Article 10 (7) MDR mandates that manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31 of the MDR.

Article 27(3) MDR mandates that before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI.

In accordance with the Basic UDI-DI and UDI-DI provisions of the MDR, triggers for both a new Basic UDI-DI and UDI-DI are defined. In particular, a new UDI-DI shall be required in the case of any change related to elements set out in Annex VI Part, C, 3.9, MDR to avoid misidentification of the device.

Bearing in mind the requirement for appropriate and uniform identification, taking into account the nature of Spectacle lenses and Ready readers and the interest of proportional data entries in EUDAMED, data elements applicable to these products and their potential triggers have been defined accordingly. Annex I & II of this document outline the Basic-UDI-DI and UDI-DI groupings to be assigned by manufacturers of spectacle lenses and ready readers.

Annex I - UDI assignment for Spectacle lenses

Spectacle Lenses	criteria / attributes				
BASIC UDI-DI Level Combination of the attributes:	**Commercial Indexes** 1.5, 1.56, 1.59, 1.6, 1.67, 1.7, 1.74, 1.8 …	**Options** photochromic, polarized, others (clear)	**Design** Single Vision, Bifocal / Multifocal, Variation Power lenses	**Lens material** mineral, organic	
UDI-DI Level Combination of the attributes:	**Commercial Indexes** 1.5, 1.56, 1.59, 1.6, 1.67, 1.7, 1.74, 1.8 …	**Options** photochromic, polarized, others (clear)	**Design** Single Vision, Bifocal / Multifocal, Variation Power lenses	**Lens material** mineral, organic	**Commercial name** e.g. „Super Lens“
UDI-PI Level	The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. For European and worldwide ophthalmic industry the UDI-PI is related to unit of device production and will be not be related to customer´s prescription parameter of the device.				

Annex II - UDI assignment for Ready readers

Ready Reader	criteria / attributes					
BASIC UDI-DI Level Combination of the attributes:	Frame construction full rim, half rim, rimless, other types	Frame material Metal, plastic, mixed, other types	Lens material mineral, organic			
UDI-DI Level Combination of the attributes:	Commercial name e.g. „Super Reader“	colour e.g. „green 02“	Lens width (A dimension) e.g. „52mm“	Nose width (DBL) e.g. „18mm“	Power e.g. „+3.00“	Lens material mineral, organic
UDI-PI Level	The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. For European and worldwide ophthalmic industry the UDI-PI is related to unit of device production and will be not be related to customer´s prescription parameter of the device.					