

MDCG 2025-8 Rev. 1

Guidance on the implementation of the Master UDI-DI solution for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

March 2026

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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| MDCG 2025-8 Rev. 1 changes | |
|-----------------------------------|--|
| Page 16 | Diagram for "Master UDI-DI assignment scheme for spectacles lenses reflecting parameters and values ranges (assignment triggers)": correction from "Advanced" to "Advanced/High" |
| Page 18 | Flowchart for "Decision trees for the assignment of Master UDI-DI" (for spectacle lenses): progression Advanced/High value corrected from "< 1,25 D" to "≥ 2.00 D" |

Table of contents

- 1. Introduction and scope 4
- 2. Terminology 5
- 3. Basic UDI-DI and Master UDI-DI 8
 - 3.1 Spectacle frames – Basic and Master UDI-DI assignment 9
 - 3.2 Spectacle lenses – Basic and Master UDI-DI assignment 14
 - 3.3 Ready-to-wear reading spectacles – Basic and Master UDI-DI assignment 21
- 4. Master UDI-DI assignment on container package, packaging levels and packaging variants 27
- 5. Vigilance reporting for spectacle frames, spectacle lenses and ready-to-wear reading spectacles 27
- 6. Timeline for the assignment, application and Eudamed registration of device’s Master UDI-DIs 28
- 7. Annex 28
 - 7.1 Spectacle frames – decision tree 29
 - 7.2 Spectacle lenses – additional infographic 31
 - 7.3 Ready-to-wear reading spectacles – decision tree 32

1. Introduction and scope

The introduction of the Unique Device Identification (UDI) system referred to in Article 27 of Regulation (EU) 2017/745 on medical devices (MDR)¹ aims to ensure an adequate level of identification and traceability with respect to medical devices. Basic UDI-DIs, UDI-DIs and UDI-PIs shall be assigned (in compliance with the rules of the designated issuing entities) by manufacturers to all devices, other than custom-made devices, prior to their placement on the market.

To further strengthen and enhance traceability and recording of UDIs, manufacturers shall register Basic UDI-DIs and UDI-DIs in the European Database on Medical Devices (Eudamed)².

For certain groups of devices that are presenting a high level of individualisation ('highly individualised devices', HID), Annex VI, Part C MDR has been amended with provisions on assignment of Master UDI-DI to HIDs. Provisions for spectacle frames, spectacle lenses and ready-to-wear reading spectacles have been introduced in Section 6.6.2 by Commission Delegated Regulation (EU) 2025/1920 on Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles³.

Master UDI-DI is intended as the identifier of a group of HID (i.e. contact lenses, spectacle frames, spectacle lenses and ready-to-wear reading spectacles) presenting specific similarities with respect to defined design (clinically and non-clinically) relevant parameters.

Even though all economic operators have to contribute according to Article 25 MDR, it is the sole responsibility of the manufacturer to comply with the UDI requirements in order to ensure an appropriate level of traceability of the device, according to Article 10(7) MDR.

This document aims to provide guidance in the implementation of Master UDI-DI rules for spectacle frames, spectacle lenses and ready-to-wear reading spectacles as regards its structure, assignment, labelling and registration in Eudamed.

NOTES: *This document is intended to be read in conjunction with Regulation (EU) 2017/745 on medical devices (MDR), Commission Delegated Regulation (EU) 2025/1920, MDCG 2025-7 position paper⁴ and MDCG guidance documents on UDI⁵.*

Information on Master UDI-DI for highly individualised devices has been collected in a specific section of the Commission webpage on Unique Device Identifier - UDI⁶.

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 5.5.2017, p. 1. Current consolidated version ELI: <https://eur-lex.europa.eu/eli/reg/2017/745/2025-01-10>).

² https://health.ec.europa.eu/medical-devices-eudamed_en.

³ 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, ready-to-wear reading spectacles (OJ L, 2025/1920, 23.9.2025, ELI: http://data.europa.eu/eli/reg_del/2025/1920/oj).

⁴ https://health.ec.europa.eu/document/download/ad6ae143-baa2-451a-8c5e-0c5d22983e88_en?filename=mdcg_2025-7_en.pdf.

⁵ https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en#sec18.

⁶ https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en#master-udi-di-for-high-individualised-devices.

2. Terminology⁷

Spectacle frame: Highly individualised device intended to hold spectacle lenses in front of the patient's eyes. As an adaptable highly individualised medical device (see MDCG 2021-3⁸, page 3), it is fitted and adjusted at the point of care according to the manufacturer's instructions. These necessary steps are traditionally carried out by an eye care professional (e.g. optician or an optometrist) to adapt to the specific anatomical features of an individual patient prior to use. The frame may be part of a combination with other highly individualised medical devices (e.g. lenses) that are assembled and shaped to form a spectacle.

Spectacle lens: Highly individualised device with an intended purpose to correct vision impairment such as eye refractive errors (myopia, hyperopia, astigmatism and presbyopia). Spectacle lenses are supplied following a prescription from an eye care professional (e.g. ophthalmologist). The spectacle lenses may be assembled and shaped to be part of a combination with another highly individualised medical device (e.g. spectacle frame) to form a spectacle.

Ready-to-wear reading spectacle: Highly individualised device intended to correct vision impairment for near vision activities and reading. The device is ready to use and is a pre-mounted non-prescription reading spectacle. This device is composed of two identical single-vision spectacle lenses with limited spherical power range assembled and shaped into a spectacle frame.

Full-rim spectacle frame: A type of spectacle in which the frame front completely surrounds the lenses with a frame material, either metal, plastic or others or a combination of it.

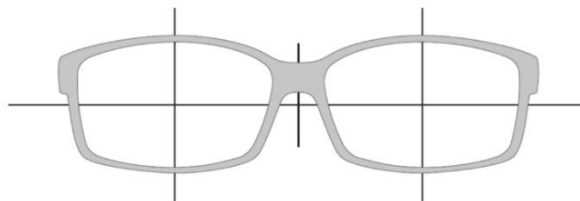


Figure 1: Example of full-rim spectacle frame (plastic)

Half-rim spectacle frame (also known as a semi-rimless spectacle frame): A spectacle frame design where only part of the lenses is enclosed by the frame, while the other part is left open or supported by a thin wire usually made of nylon material.

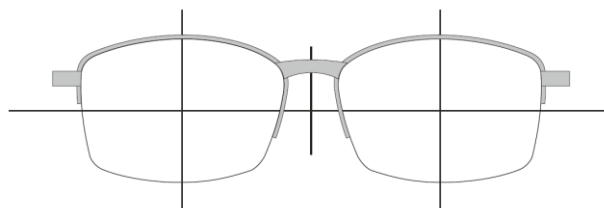


Figure 2: Example of half-rim spectacle frame (metal)

Rimless spectacle frame: A type of spectacle frame where the lenses are mounted directly to the bridge and temples without a surrounding frame usually by means of screws.

⁷ For UDI-related definitions and other terminology, see Part C of Annex VI to the MDR and international recognized standard for spectacle frame.

⁸ MDCG 2021-3 Questions and Answers on Custom-Made Devices
https://health.ec.europa.eu/document/download/385d7e20-d8b5-49d0-abd7-8daf269bf1b8_en?filename=mdcg_2021-3_en.pdf.

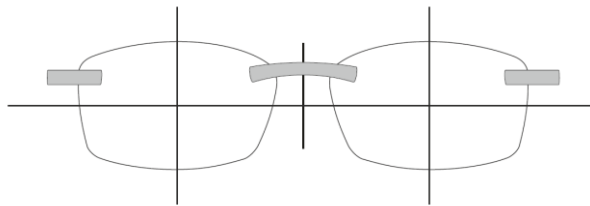


Figure 3: Example of rimless spectacle frame

Plastic spectacle frame⁹:

A spectacle frame in which at least the principal components (rims, bridge, lugs and temples) are made exclusively from synthetic or artificial materials. Common materials used for plastic frames include, but are not limited to, cellulose acetate, propionate, nylon and polycarbonate.

Metal spectacle frame¹⁰:

A spectacle frame in which at least the principal components (rims, bridge, lugs and temples) are made exclusively from metal or metal alloys. Common materials for metal frames include, but are not limited to, Monel, Stainless Steel, Titanium, Gold and Silver.

Other types frame material¹¹:

Spectacle frame in which at least the principal components (rims, bridge, lugs and temples) are neither made of metal or metal alloy nor synthetic or artificial materials. Common materials used, but are not limited to, are woods, bamboo and carbon fibre.

Combination spectacle frame¹²:

A spectacle frame in which at least the principal components (rims, bridge, lugs and temples) are made of at least two different material categories (categories of material include, but are not limited to, metal, plastic and natural organic materials). Common materials used for combination frames include, but are not limited to, Monel, stainless steel, titanium, gold, silver, cellulose acetate, propionate, nylon, polycarbonate, woods, bamboo and carbon fibre.

Organic lenses: Uncut (round) spectacle lenses with both sides optically worked and finished made of plastic polymer materials.

Mineral lenses: Uncut (round) spectacle lenses with both sides optically worked and finished made of glass material.

⁹ The definition is based on internationally recognised standards applicable to spectacle frames. The definition excludes all components other than the principal component, for example, but not limited to, nose pads, end covers (tips) and coatings.

¹⁰ The definition is based on internationally recognised standards applicable to spectacle frames. The definition excludes all components other than the principal component, for example, but not limited to, nose pads, end covers (tips) and coatings.

¹¹ The definition is based on internationally recognised standards applicable to spectacle frames. The definition excludes all components other than the principal component, for example, but not limited to, nose pads, end covers (tips) and coatings.

¹² The definition is based on internationally recognised standards applicable to spectacle frames. The definition excludes all components other than the principal component, for example, but not limited to, nose pads, end covers (tips) and coatings.

Basic UDI-DI: Primary identifier of device sharing the same intended purpose, risk class and same essential design characteristics. It is the main key for records in the UDI database and is referenced in the EU declaration of conformity. It is not to be reflected on device label.

Master UDI-DI: Unique identifier used for grouping certain devices presenting a high level of individualisation ('highly individualised devices', HID) as for spectacle frames, spectacle lenses and ready-to-wear reading spectacles as defined in Commission Delegated Regulation (EU) 2025/1920. It is acting as UDI-DI as defined in Part C of Annex VI to the MDR. Such HID share the same combination of design parameters (clinical and non-clinical). It is the access key to the device dataset registered in Eudamed. Master UDI-DI assignment for manufacturer should follow the rules defined in the following documents and reflected in this guidance document:

- Regulation (EU) 2017/745 (MDR)
- Commission Delegated Regulation (EU) 2025/1920
- EU designated issuing entities standard.

UDI-PI: according to MDR Annex VI, Part C, Section 1, the different types of UDI-PIs include lot number and/or manufacturing date among others. The UDI (Master UDI-DI + UDI-PI) intends to enable the automatic identification of the individual device to conform with the MDR UDI requirements.

3. Basic UDI-DI and Master UDI-DI

Assignment rules of UDI-DI per the MDR is defined in its Annex VI, Part C, Section 3.9. However, the assignment rules of Master UDI-DI differ from the assignment rules of UDI-DI. It also affects the triggers which requires the assignment of a new UDI-DI per MDR.

Master UDI-DI is acting as UDI-DI and should be assigned to devices sharing the same essential design characteristics, the same intended purpose and the same combination of design parameters.

The table below compares different device identifiers given by the assignment of Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

Overview of the Unique Device Identifiers for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

| Identifiers | Spectacle frame, spectacle lenses, ready-to-wear reading spectacle | On the device label | In Eudamed |
|--|--|---------------------|------------------|
| Basic UDI-DI | Yes | No | Yes |
| Master UDI-DI | Yes | Yes | Yes |
| UDI-PI | Yes | Yes | No ¹³ |
| <ul style="list-style-type: none"> • Master UDI-DI and UDI-PI forms the UDI per EU MDR 2017/745 • Manufacturer's Basic UDI-DI and Master UDI-DI are linked to the manufacturer. • Each combination of Basic UDI-DI parameter values forms the scope of 1 Basic UDI-DI • 1 Master UDI-DI is assigned to a device sharing the same combination of Basic UDI-DI parameters values and Master UDI-DI design parameters (discrete values or within a same defined values range) • 1 Master UDI-DI can be linked to only 1 Basic UDI-DI but 1 Basic UDI-DI can be linked to multiple Master UDI-DIs | | | |

¹³ The UDI-PI Type (e.g. lot number, manufacturing date...) is registered in the Eudamed UDI/Device registration module. UDI value(s) is(are) reported in the Eudamed Vigilance and Post-Market Surveillance modules in case of serious incidents.

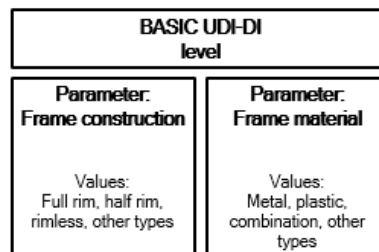
3.1 Spectacle frames – Basic and Master UDI-DI assignment

Basic UDI-DI

Basic UDI-DI assignment for spectacle frames is defined by a combination of 2 parameters with their respective values (assignment triggers):

| Parameters | Values (assignment triggers) |
|--------------------|---|
| Frame construction | Full-rim, half-rim, rimless, other types |
| Frame material | Metal, plastic, Combination, other types |

Basic UDI-DI assignment scheme for spectacle frames reflecting parameters and values (assignment triggers):

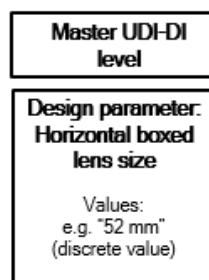


Master UDI-DI

Commission Delegated Regulation (EU) 2025/1920: “A UDI-DI shall be assigned to spectacle frames that have the same combination of design parameters, including at least the horizontal boxed lens size (“Master UDI-DI”).

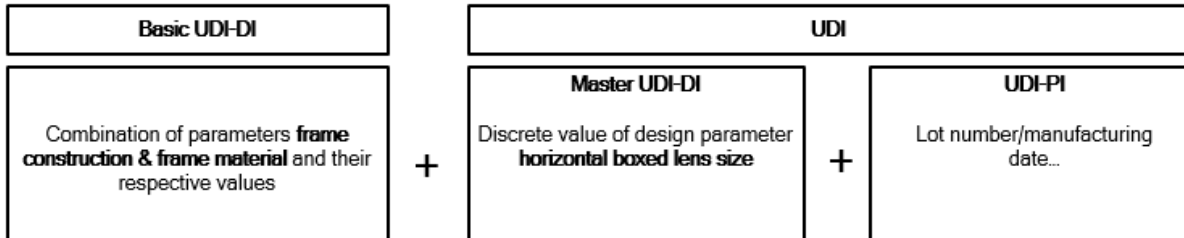
Master UDI-DI design parameter is the horizontal boxed lens size with discrete values in a typical range **between 40 mm and 60 mm** (assignment triggers).

Master UDI-DI assignment for spectacle frames is a combination of 2 Basic UDI-DI parameters values and a Master UDI-DI design parameter value (assignment trigger):



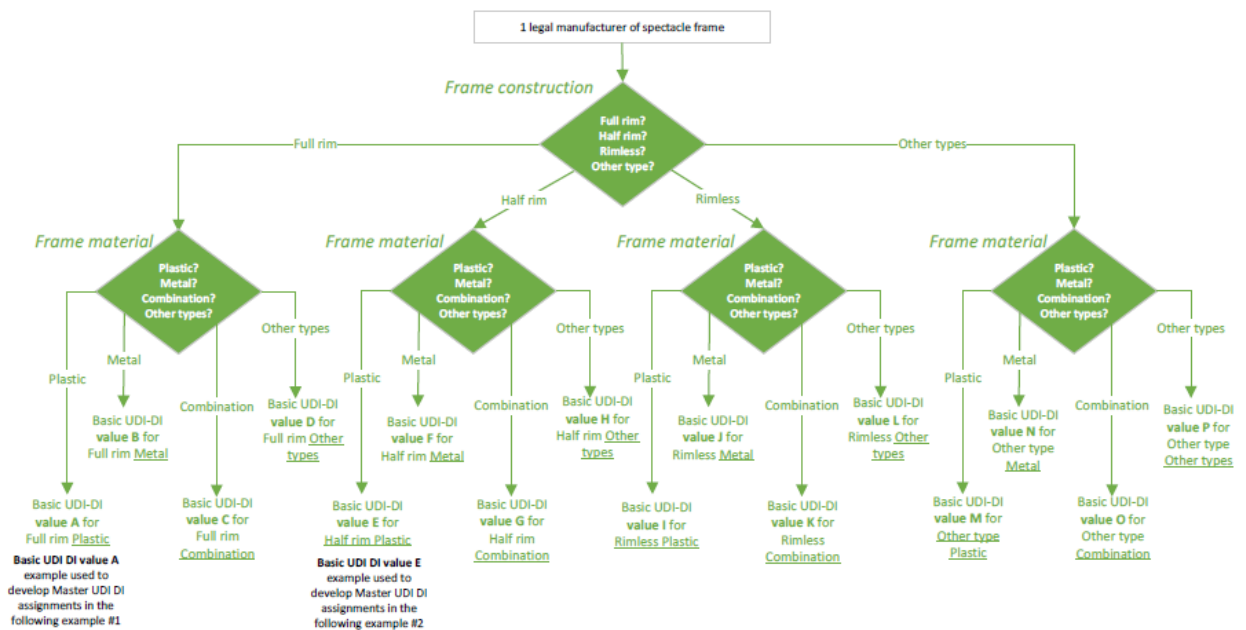
Basic UDI-DI and Master UDI-DI

Basic UDI-DI and Master UDI-DI assignment scheme for spectacle frames reflecting parameters and values (assignment triggers) + UDI-PI:



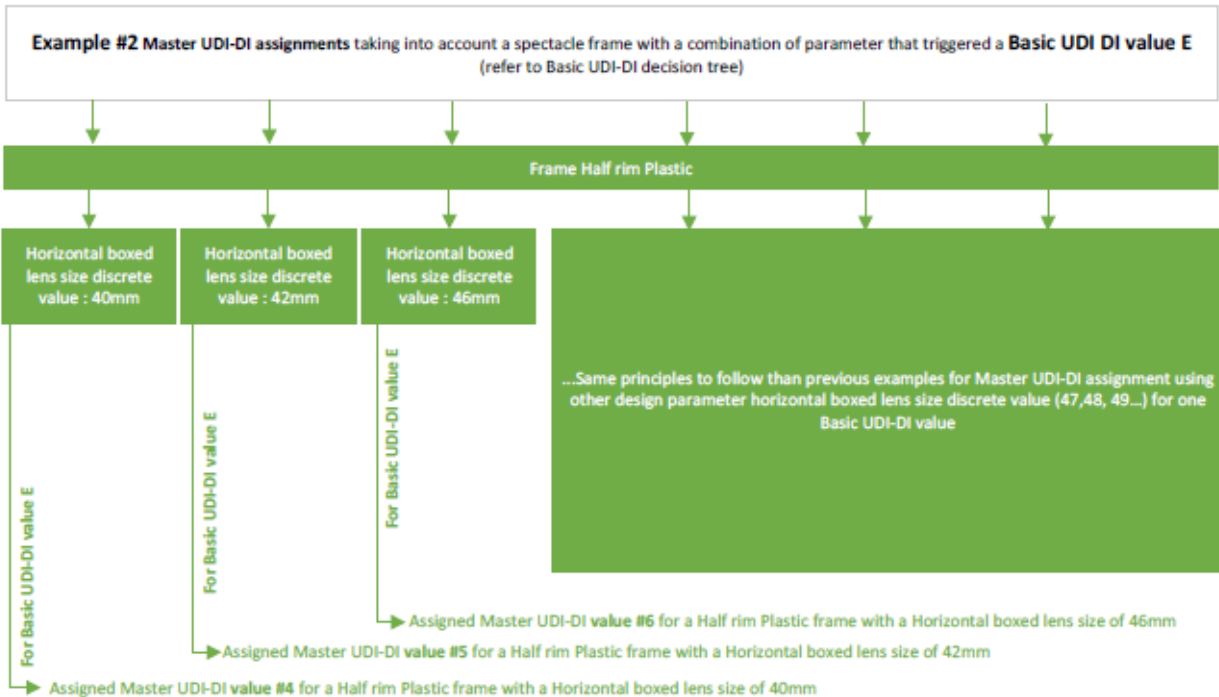
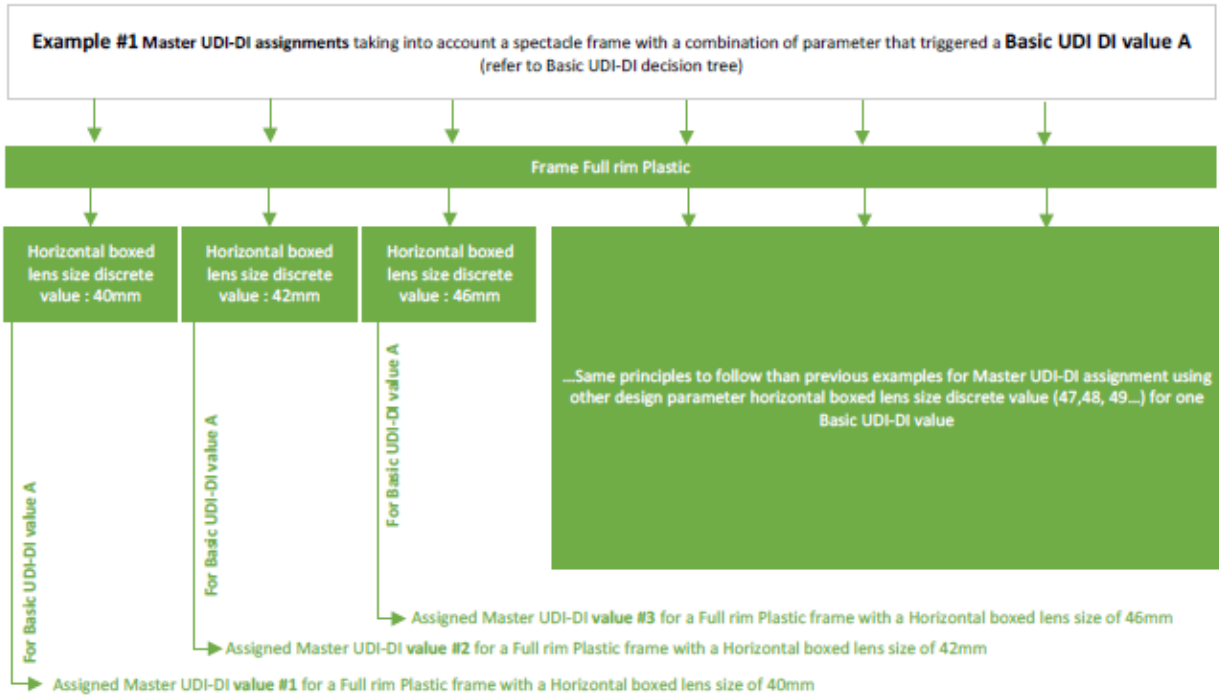
Decision tree for the assignment of Basic UDI-DI

A decision tree for the assignment of the Basic UDI-DI for spectacle frames is shown below. Another version of the decision tree, which includes the Master UDI-DI assignment, is available in the Annex.



Decisions trees for the assignment of Master UDI-DI

Decision trees for the assignment of Master UDI-DIs for spectacle frames taking as examples a Basic UDI-DI with a value A and a Basic UDI-DI with a value E previously developed in Basic UDI-DI decision tree are shown below.



Master UDI-DI assignment for spectacle frames: concrete examples

| Examples Spectacle frames | 1 manufacturer (1 SRN). Brands and device model reference (catalogue number) * | Basic UDI-DI parameters value combination (assignment triggers) | Basic UDI-DI value (e.g. GS1 GMN) reflecting 1 Basic UDI-DI combination of parameter values | Master UDI-DI design parameter value (horizontal boxed lens size as assignment trigger) | Different Master UDI-DI value (e.g. GS1) based on Basic UDI value and Master UDI design parameter value |
|---------------------------|--|---|---|---|---|
| #1 | Manufacturer 1, Brand A Model ref A | Rimless, Combination | Basic UDI-DI #1 | 50 | M-UDI-DI #1 |
| #2 | Manufacturer 1, Brand A Model ref B | Rimless, combination | Basic UDI-DI #1 | 50 | M-UDI-DI #1 |
| #3 | Manufacturer 1, Brand A Model ref A | Rimless, combination | Basic UDI-DI #1 | <u>52</u> | M-UDI-DI #2 |
| #4 | Manufacturer 1, Brand B Model ref C | Rimless, combination | Basic UDI-DI #1 | <u>48</u> | M-UDI-DI #3 |
| #5 | Manufacturer 1, Brand A Model ref A | Full-rim , combination | Basic UDI-DI #2 | <u>50</u> | M-UDI-DI #4 |
| #6 | Manufacturer 1, Brand C Model ref B | Full-rim, combination | Basic UDI-DI #2 | <u>51</u> | M-UDI-DI #5 |
| #7 | Manufacturer 1, Brand A Model ref A | Full-rim, plastic | Basic UDI-DI #3 | <u>50</u> | M-UDI-DI #6 |
| #8 | Manufacturer 1, Brand C Model ref B | Full-rim, plastic | Basic UDI-DI #3 | 50 | M-UDI-DI #6 |
| #9 | Manufacturer 1, Brand E Model ref A | Half-rim, metal | Basic UDI-DI #4 | <u>48</u> | M-UDI-DI #7 |

Note: Parameters in **bold** and underlined in 1 example reflect Basic UDI-DI and/or Master UDI-DI assignment triggers compared to the previous example.

*Different spectacle frame brands/trademarks and catalogue numbers are not Master UDI-DI assignment triggers

Labelling for spectacle frames

The rules on UDI carrier in Section 4 of Part C of Annex VI to the MDR and relevant issuing entity (for instance GS1) standard shall apply to the Master UDI-DI.

The label layout shown below is for illustrative purposes only, to show how the UDI (Master UDI-DI + UDI-PI) might appear, and does not reflect a requirement to align the exact layout of the device label as shown, or as a presumption of compliance with the MDR or any other regulatory requirements.

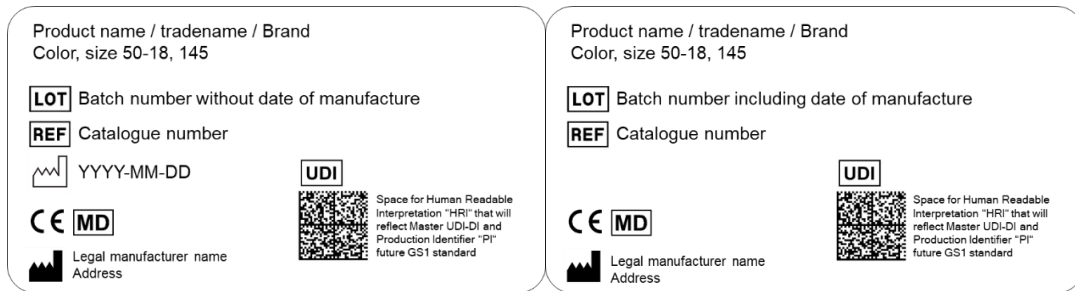


Figure 4: Labelling example for spectacle frames with or without date of manufacture included in the LOT number

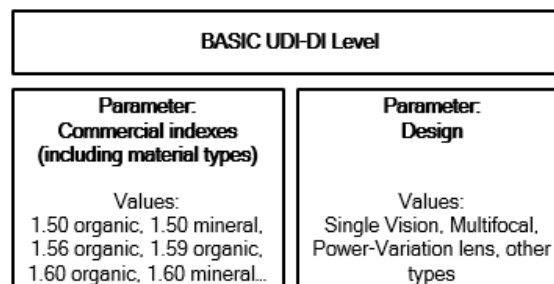
3.2 Spectacle lenses – Basic and Master UDI-DI assignment

Basic UDI-DI

Basic UDI-DI assignment for spectacle lenses is defined by 2 parameters with their respective values (assignment triggers):

| Parameters | Values (assignment triggers) |
|--|---|
| Commercial indexes ¹⁴ (including lens material types) | Discrete values in a typical range between $n_e^{15} = 1.50$ and $n_e = 1.90$ and whether lens material is organic or mineral |
| Design | Single vision, multifocal, power variation lens, other types |

Basic UDI-DI assignment scheme for spectacle lenses reflecting parameters and values (assignment triggers):



Master UDI-DI

Commission Delegated Regulation (EU) 2025/1920: “A UDI-DI shall be assigned to spectacle lenses that have the same combination of design parameters, including at least groups of mean spheres (spherical equivalent power), groups of addition power and groups of similar vision impairments (‘Master UDI-DI’).

Master UDI-DI design parameters for assignment are based on intended purpose of a spectacle lens to correct vision impairments, defined by its nominal prescription (spherical power, cylinder if applicable and addition if applicable) expressed in groups of spherical equivalent power values range and 3 groups of addition values range.

¹⁴ Commercial indexes are seen with precision of 2 digits after comma (e.g. 1.52).

¹⁵ Refractive index expressed in e ray (n_e) according to applicable standards.

Master UDI-DI assignment rules

For spectacle lenses of a nominal prescription to be manufactured, spherical equivalent power (mean sphere) is thus expressed by the formula:

$$M = \text{Spherical power in dioptres} + (\text{cylinder in dioptres}/2)$$

This formula can be applied whatever a nominal cylinder is prescribed or not for a patient.

Spherical equivalent power calculation examples:

- Example n° 1: Prescribed spectacle lens of +2.00 D (cylinder = 0.00 D)
 $M = +2.00 \text{ D} + (0/2) = +2.00 \text{ D}$
- Example n° 2: Prescribed spectacle lens of +1.00 D (+2.00D) equivalent to +3.00 D (-2.00 D)
 $M = +1.00 \text{ D} + (+2.00 \text{ D}/2)$ or $+3.00 \text{ D} + (-2.00 \text{ D}/2) = +2.00 \text{ D}$
- Example n° 3: Prescribed spectacle lens of -2.00 D (+4.00) equivalent to +2.00 D (-4.00)
 $M = -2.00 \text{ D} + (+4.00 \text{ D}/2)$ or $+2.00 \text{ D} + (-4.00 \text{ D}/2) = 0.00 \text{ D}$

The result of spherical equivalent power allows to position the spectacle lens in a typical spectacle lens spherical equivalent power values range intended to correct specific vision impairment group categories that are specified as follows:

- **Spherical equivalent power values range < 0.00 D without prescribed cylinder** are spherical or aspherical spectacle lens in concave minus range and are usually prescribed to correct vision impairment myopia.
- **Spherical equivalent power values range < 0.00 D with prescribed cylinder** are toric spectacle lens still in concave minus range but are usually prescribed to correct vision impairment myopia + astigmatism.
- **Spherical equivalent power value = 0.00 D without prescribed cylinder** are spherical or aspherical spectacle lens in afocal range and are usually prescribed when one patient's eye does not need correction seen as emmetropia, but the other patient eye does.
- **Spherical equivalent power value = 0.00 D with prescribed cylinder** are toric spectacle lens still in afocal range and are usually prescribed when one patient's eye does need a correction for vision impairment emmetropia + astigmatism.
- **Spherical equivalent power values range > 0.00D without prescribed cylinder** are spherical or aspherical spectacle lens in convex positive range and are usually prescribed to correct vision impairment hyperopia.
- **Spherical equivalent power values range > 0.00D with prescribed cylinder** are toric spectacle lens still in convex positive range and are usually prescribed to correct vision impairment hyperopia + astigmatism.

Another spectacle lens design parameter to consider, if applicable, is addition in dioptres that can be prescribed to complement one of the 6 vision impairment group categories mentioned previously. This spectacle lens is either power variation or multifocal lens usually to correct additional vision impairment presbyopia. This parameter for Master UDI-DI assignment is split

in **3 groups of addition values range, Mild/Low, Moderate, Advanced/High** specified as follows:

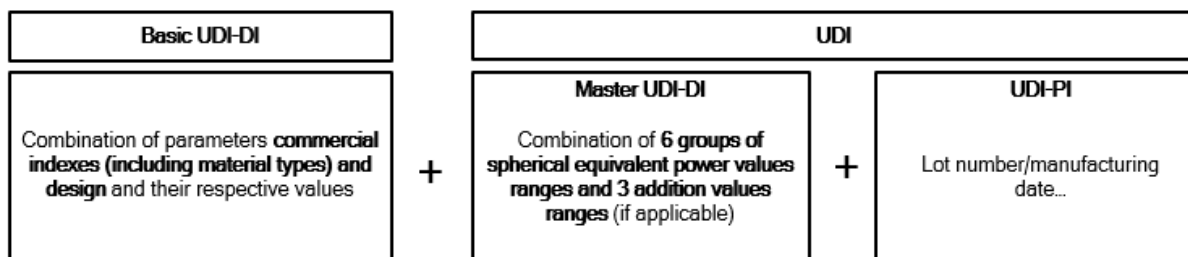
- **Mild/Low** presbyopia with a typical nominal prescribed addition value in range (assignment trigger) **between > 0.00 D and < 1.25 D**
- **Moderate** presbyopia with a typical nominal prescribed addition value in range (assignment trigger) **between ≥ 1.25 D and < 2.00 D**
- **Advanced/High** presbyopia with a typical nominal prescribed addition value in range (assignment trigger) **≥ 2.00 D**

For one combination of Basic UDI-DI parameters values (assignment triggers) and taking into account the spectacle lens prescription, the manufacturer will assign a Master UDI-DI to the spectacle lens based on its intended purpose link to vision impairments. Its intended purpose start with its initial nominal prescription (spherical power, cylinder) expressed in a **spherical equivalent power range** (assignment trigger) and in **group of additions values range** if applicable (assignment trigger).

Master UDI-DI assignment scheme for spectacles lenses reflecting parameters and values ranges (assignment triggers):

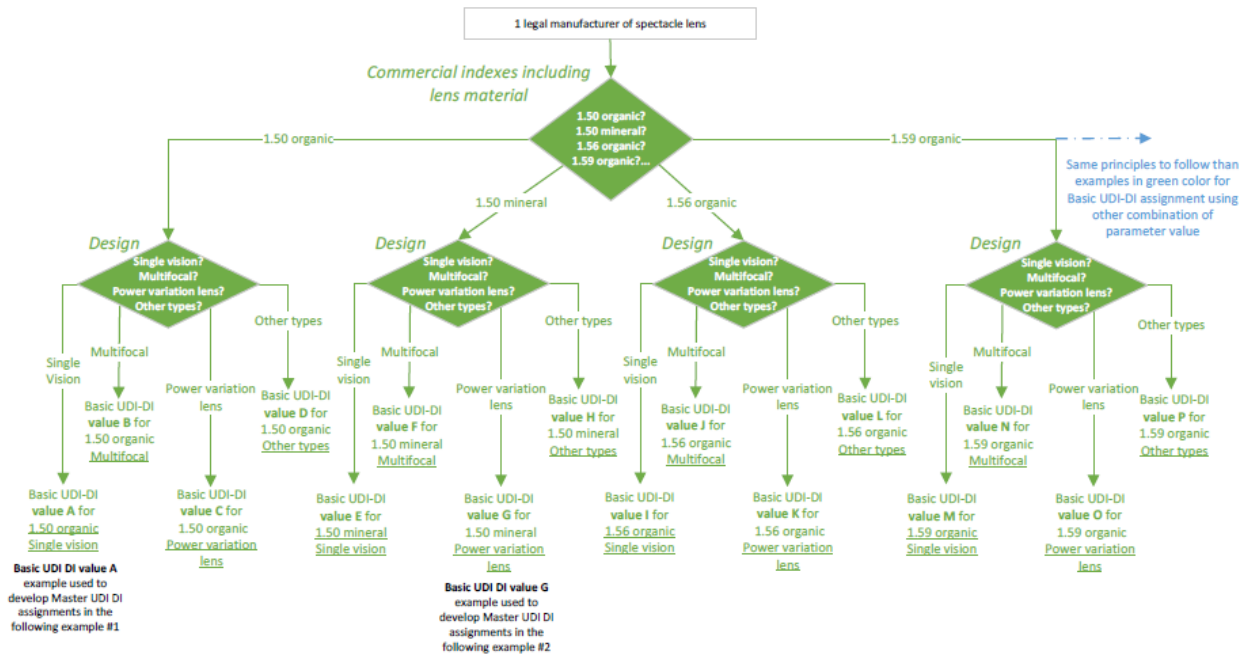
| Master UDI-DI level | | |
|--|--|--|
| Parameter: Spherical equivalent power | | Parameter: Addition |
| Without cylinder prescribed | With cylinder prescribed | Values ranges: Mild/Low -> 0,00D and < 1,25D Moderate -> $\geq 1,25$ D and < 2,00D Advanced/High -> $\geq 2,00$ D |
| Values ranges: <0,00D =0,00D >0,00D | Values ranges: <0,00D =0,00D >0,00D | |

Basic UDI-DI and Master UDI-DI assignment scheme for spectacle lenses reflecting parameters and value ranges (assignment triggers) + UDI-PI:



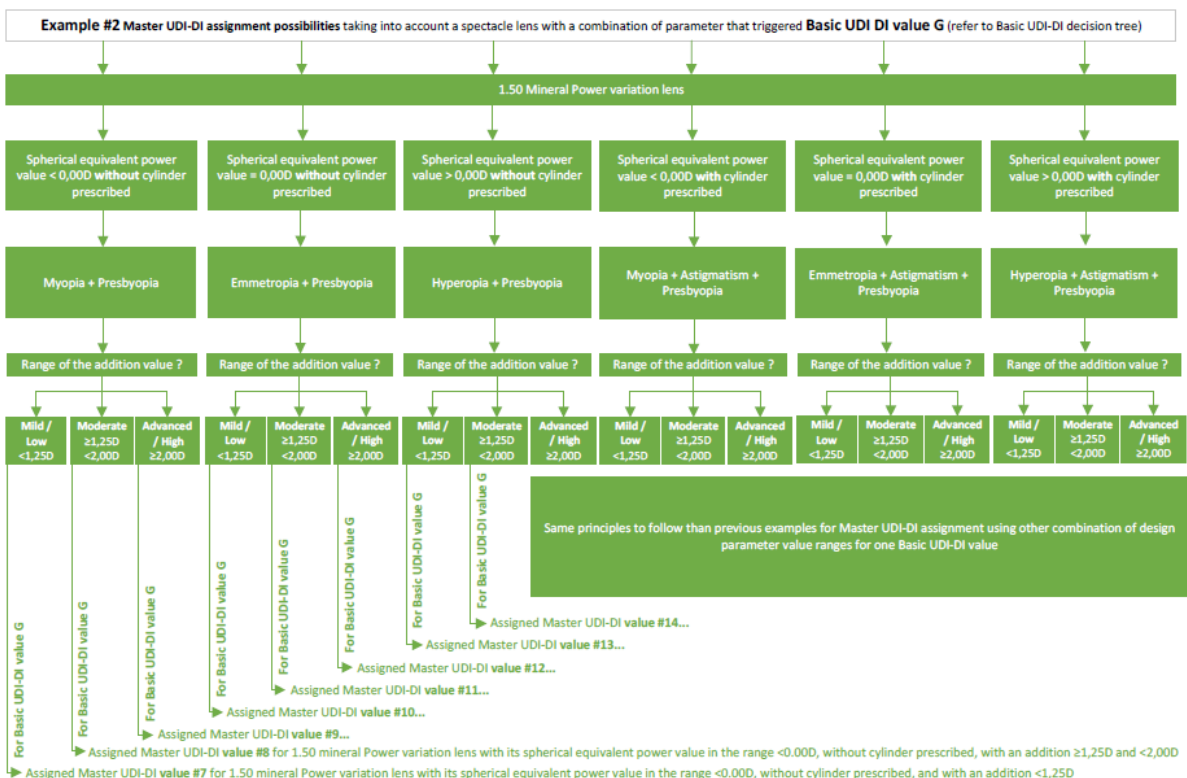
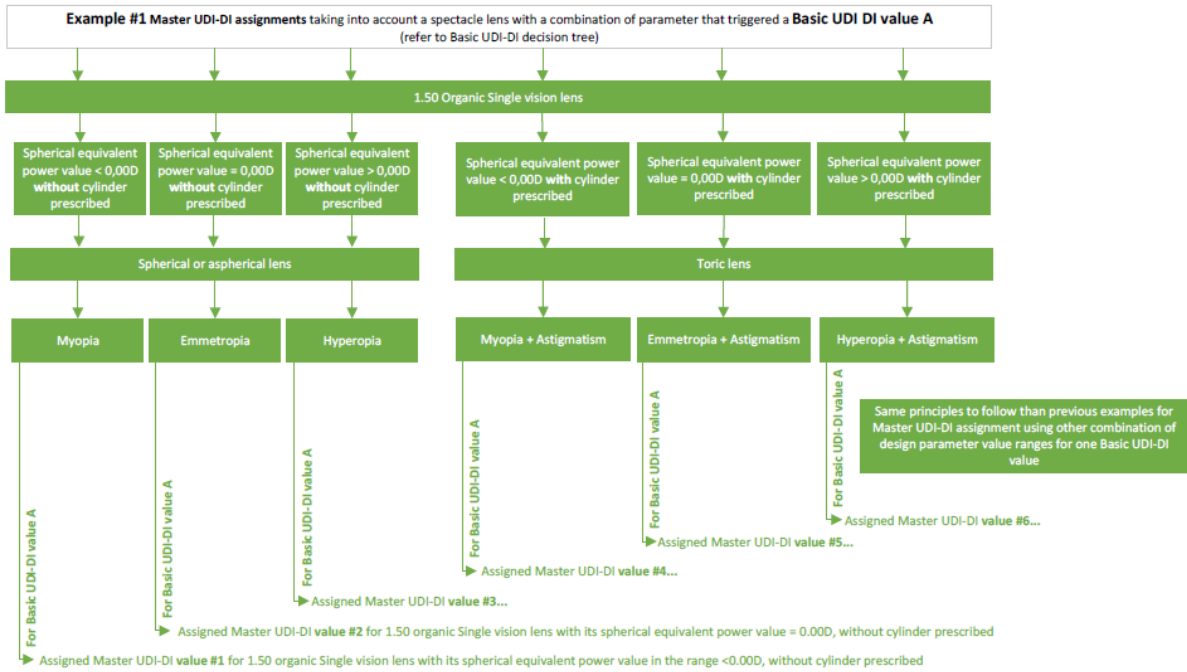
Decision tree for the assignment of Basic UDI-DI

A decision tree for the assignment of the Basic UDI for spectacle lenses is shown below.



Decision trees for the assignment of Master UDI-DI

Decision trees for the assignment of Master UDI-DIs for spectacle lenses taking as examples a Basic UDI-DI with a value A and a Basic UDI-DI with a value G previously developed in Basic UDI-DI decision tree are shown below.



Master UDI-DI assignment for spectacle lenses: concrete examples

| Examples Spectacle lens | 1 Manufacturer (1 SRN) Brands and device model reference (catalogue number) * | Nominal prescription including transposition from cyl (+) to cyl (-) (when applicable) | Basic UDI-DI parameters value combination (assignment triggers) | Basic UDI-DI value (e.g. GS1 GMN) reflecting 1 Basic UDI-DI combination of parameters value | Spherical equivalent power value and addition values (if applicable) (assignment triggers) | Vision impairment resulting from lens spherical equivalent power value range + Group of addition value range (if applicable) | Master UDI-DI assignment based on Basic UDI value and Master UDI design parameters value range |
|-------------------------|---|--|---|---|--|--|--|
| #1 | Manufacturer 1, Brand A, Model ref A | +2,00D | Lens: 1,50 organic, single vision, | Basic UDI-DI #1 | +2,00D spherical | Hyperopia | M-UDI-DI #1 |
| #2 | Manufacturer 1, Brand B, Model ref B | +2,00D | Lens: 1,50 organic, single vision, | Basic UDI-DI #1 | +2,00D spherical | Hyperopia | M-UDI-DI #1 |
| #3 | Manufacturer 1, Brand B, Model ref B | +1,00D | Lens: 1,60 organic , single vision, | Basic UDI-DI #2 | +1,00D spherical | Hyperopia | M-UDI-DI #2 |
| #4 | Manufacturer 1, Brand B, Model ref B | +0,00D (+2,00) or +2,00D (-2,00) | Lens: 1,60 organic, single vision, | Basic UDI-DI #2 | +1,00D toric | Hyperopia + astigmatism | M-UDI-DI #3 |
| #5 | Manufacturer 1, Brand B, Model ref B | -1,00D (+3,25) or +2,25D (-3,25) | Lens: 1,60 organic, single vision | Basic UDI-DI #2 | +0,625D toric | Hyperopia + astigmatism | M-UDI-DI #3 |
| #6 | Manufacturer 1, Brand B, Model ref B | 0,00D | Lens: 1,60 organic, single vision | Basic UDI-DI #2 | 0,00D spherical | Emmetropia | M-UDI-DI #4 |
| #7 | Manufacturer 1, Brand A, Model ref A | -2,00D (+4,00) or +2,00D (-4,00) | Lens: 1,60 organic, single vision | Basic UDI-DI #2 | 0,00D toric | Emmetropia + astigmatism | M-UDI-DI #5 |
| #8 | Manufacturer 1, Brand A, Model ref A | -2,00D | Lens: 1,60 organic, single vision | Basic UDI-DI #2 | -2,00D spherical | Myopia | M-UDI-DI #6 |
| #9 | Manufacturer 1, Brand A, Model ref A | -2,25D (+0,50) or -1,75D (-0,50) | Lens: 1,60 organic, single vision | Basic UDI-DI #2 | -2,00D toric | Myopia + astigmatism | M-UDI-DI #7 |
| #10 | Manufacturer 1, Brand A, Model ref A | -0,50D (+2,00) or +1,50D (-2,00) / add 1,25D | Lens: 1,60 organic, power variation lens | Basic UDI-DI #3 | +0,50 toric + addition 1,25D | Hyperopia + astigmatism + presbyopia "moderate" | M-UDI-DI #8 |
| #11 | Manufacturer 1, Brand A, Model ref A | -0,50D (+2,00) or +1,50D (-2,00) / add 2,25D | Lens: 1,60 organic clear, power variation lens | Basic UDI-DI #3 | +0,50 toric + addition 2,25D | Hyperopia + astigmatism + presbyopia "advanced/high" | M-UDI-DI #9 |

Note: Parameters in **bold** and underlined in 1 example reflect Basic UDI-DI and/or Master UDI-DI assignment triggers compared to the previous example.

* Different spectacle lens brands/trademarks and catalogue number are not Master UDI-DI assignment triggers

Labelling for spectacle lenses

The rules on UDI carrier in section 4 of Part C of Annex VI to the MDR and relevant issuing entity (for instance GS1) standard shall apply to the Master UDI-DI.

The labels layout presented below are for illustrative purposes only to reflect how the UDI (Master UDI-DI + UDI-PI) might appear and does not reflect a requirement to align device labelling exact layout as shown, or seen as a presumption of conformity to the MDR or any other regulatory requirements.

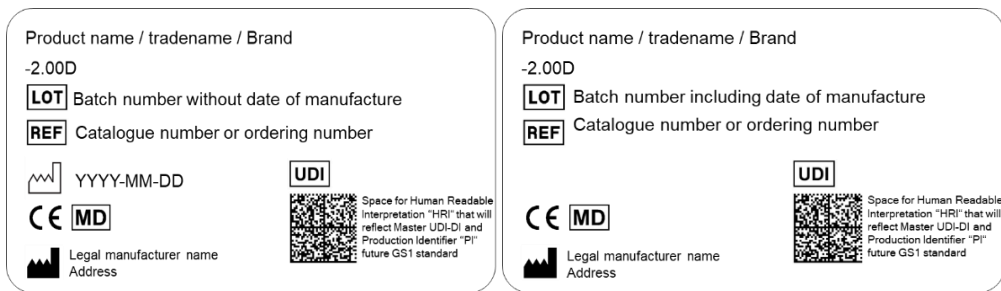


Figure 5: Labelling example for spectacle lenses with or without date of manufacture included in the LOT number

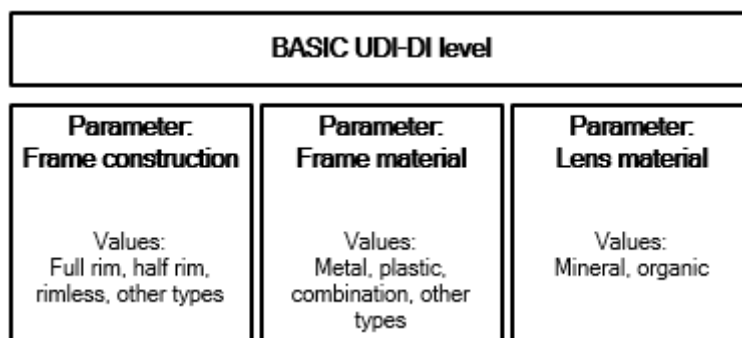
3.3 Ready-to-wear reading spectacles – Basic and Master UDI-DI assignment

Basic UDI-DI

Basic UDI-DI assignment for ready-to-wear reading spectacles is defined by a combination of 3 parameters with their respective values (assignment triggers):

| Parameter | Values (assignment triggers) |
|--------------------|---|
| Frame construction | Full-rim, half-rim, rimless, other types |
| Frame material | Metal, plastic, combination, other types |
| Lens material | Mineral, organic (including polycarbonate) |

Basic UDI-DI assignment scheme reflecting parameters and values (assignment triggers):



Master UDI-DI

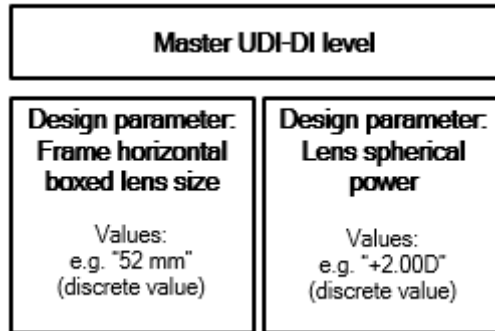
Commission Delegated Regulation (EU) 2025/1920: “A UDI-DI shall be assigned to ready-to-wear reading spectacles that have the same combination of design parameters, including at least the horizontal boxed lens size and lens spherical power (‘Master UDI-DI’)”.

Master UDI-DI assignment for ready-to-wear reading spectacles is a combination of 3 Basic UDI-DI parameters and 2 Master UDI-DI design parameters, each with their respective values.

Master UDI-DI design parameter:

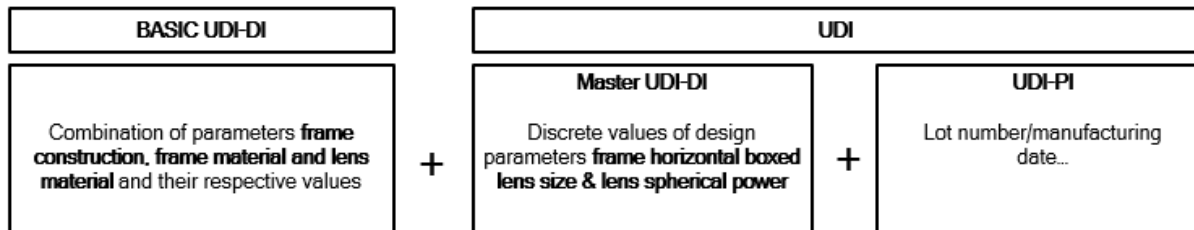
- **Frame horizontal boxed lens size** with discrete values in a typical range between **40 mm and 60 mm (assignment triggers)**
- Lens **spherical power** with discrete values in the range: **+1.00 D to +3.50 D (assignment triggers)**

Ready to wear reading spectacles Master UDI-DI assignment scheme:



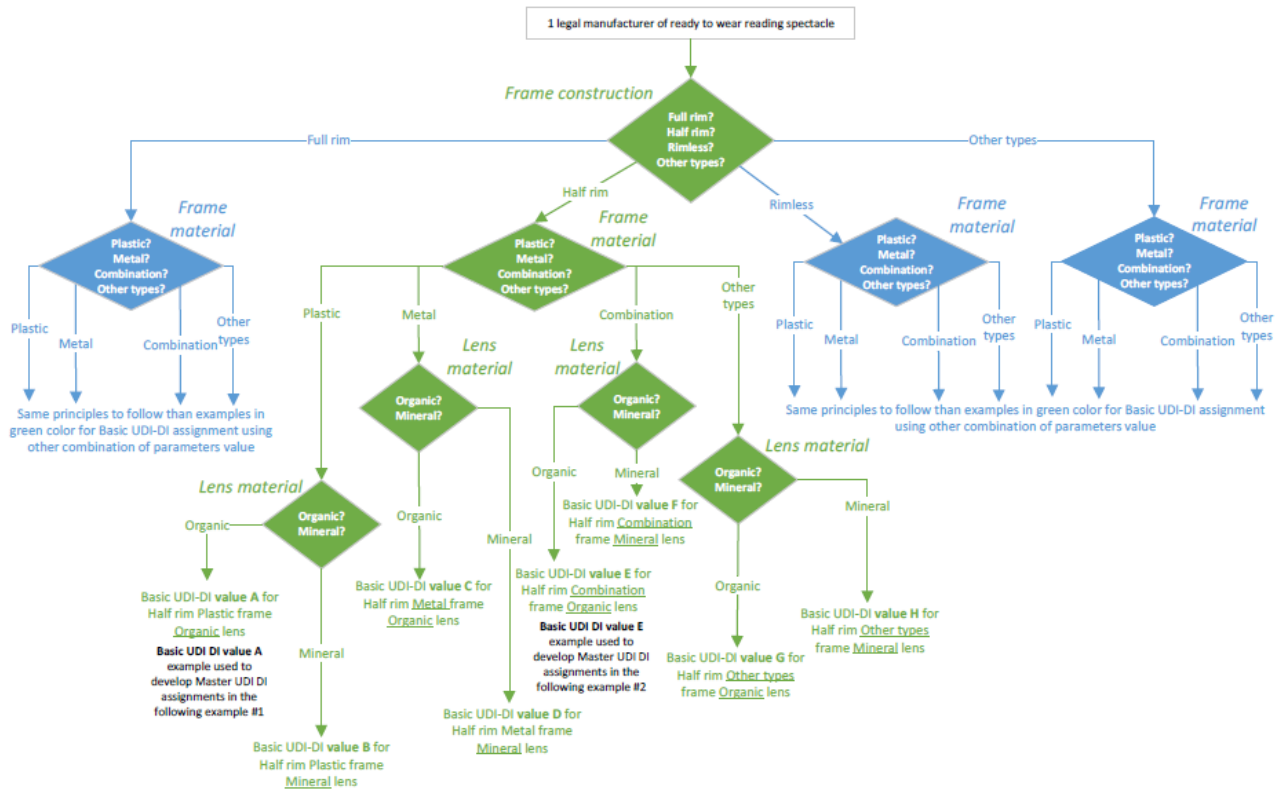
Basic UDI-DI and Master UDI-DI

Basic UDI-DI and Master UDI-DI assignment scheme for ready-to wear reading spectacles reflecting parameter and values (assignment triggers) + UDI-PI:



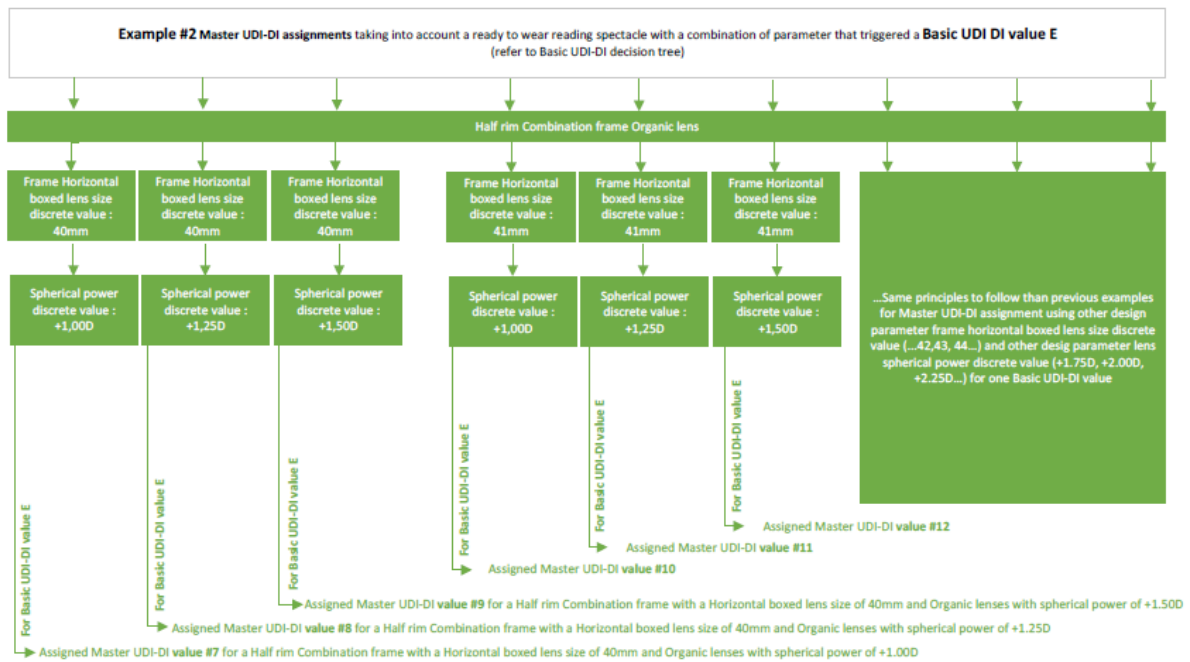
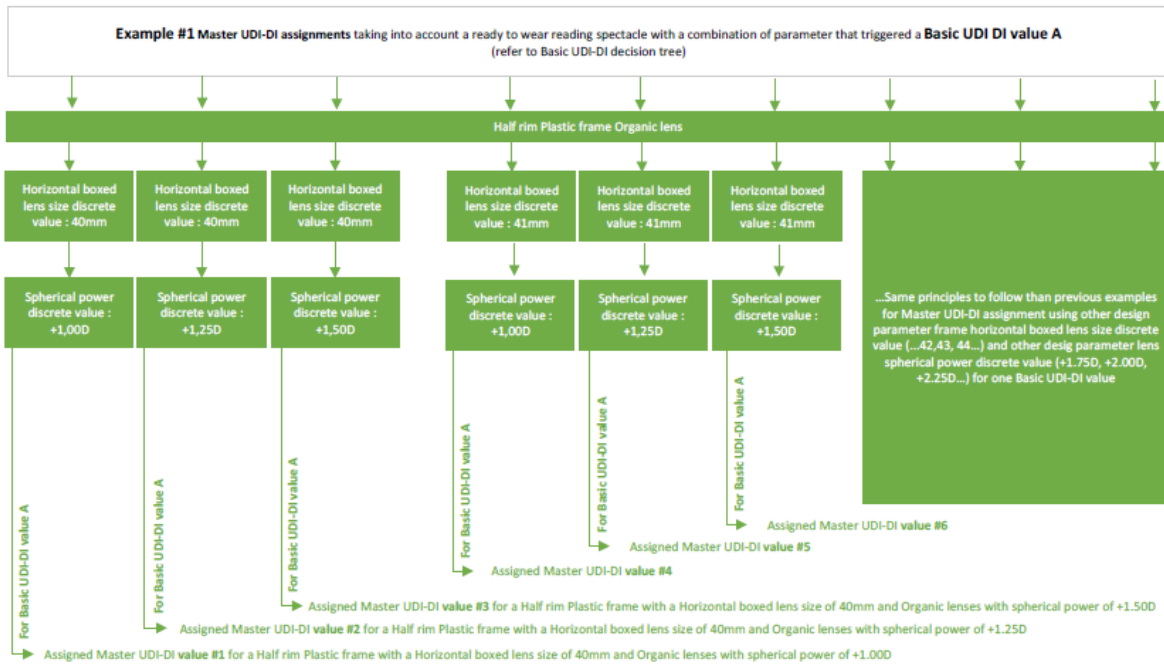
Decision tree for the assignment of Basic UDI-DI

A decision tree for the assignment of the Basic UDI for ready-to-wear reading spectacles is shown below. Another version of the decision tree, which includes the Master UDI assignment, is available in the Annex.



Decision trees for the assignment of Master UDI-DI

Decision trees for the assignment of Master UDI-DIs for ready-to-wear reading spectacles taking as examples a Basic UDI-DI with a value A and a Basic UDI-DI with a value E previously developed in Basic UDI-DI decision tree are shown below.



Master UDI-DI assignment for ready-to-wear reading spectacles: concrete examples

| Examples Ready to wear reading spectacles | 1 manufacturer (1 SRN). Brand and device model reference (catalogue number) * | Basic UDI-DI parameters value combination (assignment triggers) | Basic UDI-DI value (e.g. GS1 GMN) reflecting 1 Basic UDI-DI combination of parameters value | Master UDI-DI design parameter value for horizontal boxed lens size (assignment trigger) | Master UDI-DI design parameter value for spherical power (assignment triggers) | Different Master UDI-DI assignment (e.g. GS1) based on Basic UDI value and Master UDI design parameters value |
|--|---|---|---|--|--|---|
| #1 | Manufacturer 1, Brand A Model ref A | Frame: Half-rim, combination, Lens: organic | Basic UDI-DI #1 | 50 | +3.00 | M-UDI-DI #1 |
| #2 | Manufacturer 1, Brand A Model ref B | Frame: Half-rim, combination, Lens: organic | Basic UDI-DI #1 | 50 | +3.00 | M-UDI-DI #1 |
| #3 | Manufacturer 1, Brand A Model ref B | Frame: Half-rim, combination, Lens: organic | Basic UDI-DI #1 | <u>52</u> | +3.00 | M-UDI-DI #2 |
| #4 | Manufacturer 1, Brand C Model ref B | Frame: Half-rim, combination, Lens: organic | Basic UDI-DI #1 | 52 | +3.00 | M-UDI-DI #2 |
| #5 | Manufacturer 1, Brand B Model ref C | Frame: Half-rim, combination, Lens: organic | Basic UDI-DI #1 | <u>48</u> | +3.00 | M-UDI-DI #3 |
| #6 | Manufacturer 1, Brand B Model ref C | Frame: Half-rim, combination, Lens: <u>mineral</u> | Basic UDI-DI #2 | 48 | + 3.00 | M-UDI-DI #4 |
| #7 | Manufacturer 1, Brand A Model ref A | Frame: <u>Full-rim</u> , combination, Lens: mineral | Basic UDI-DI #3 | 48 | <u>+2.50</u> | M-UDI-DI #5 |
| #8 | Manufacturer 1, Brand A Model ref A | Frame: Full-rim, combination, Lens: mineral | Basic UDI-DI #3 | 48 | <u>+1.50</u> | M-UDI-DI #6 |

Note: Parameters in **bold** and underlined in 1 example reflect Basic UDI-DI and/or Master UDI-DI assignment triggers compared to the previous example.

* Different spectacle ready to wear reading spectacles brands/trademarks and catalogue numbers are not Master UDI-DI assignment triggers

Labelling for ready-to-wear reading spectacles

The rules on UDI carrier in section 4 of Part C of Annex VI to the MDR and relevant issuing entity (for instance GS1) standard shall apply to the Master UDI-DI.

The label layout shown below is for illustrative purposes only, to show how the UDI (Master UDI-DI + UDI-PI) might appear, and does not reflect a requirement to align the exact layout of the device label as shown, or as a presumption of compliance with the MDR or any other regulatory requirements.

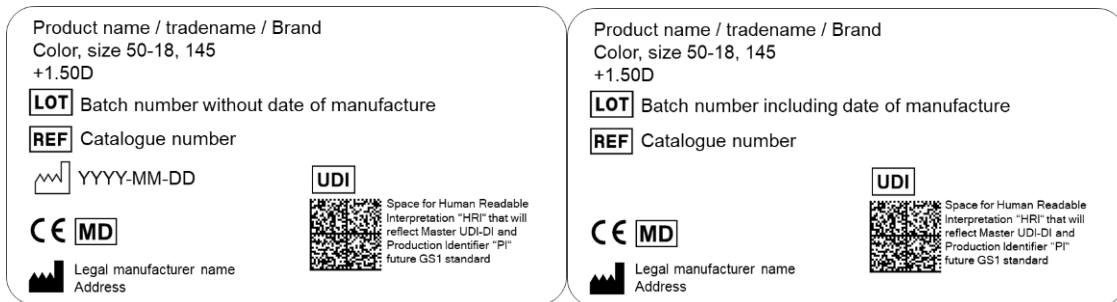


Figure 6: Labelling example for ready to wear reading spectacles with or without date of manufacture included in the LOT number

4. Master UDI-DI assignment on container package, packaging levels and packaging variants

According to Part C of Annex VI to the MDR, higher levels of packaging must have their own UDI-DI. As the Master UDI-DI replaces the UDI-DI for spectacle frames, spectacle lens and ready-to-wear reading spectacles, higher levels of packaging must have their own Master UDI-DI, if applicable.

Spectacle frames, spectacle lenses and ready-to-wear reading spectacles: Typically 1 sale/trade unit corresponds to 1 spectacle frame or 1 spectacle lens or 1 ready-to-wear reading spectacle. Hence, higher levels of packaging than device packaging (cartons) are typically containing frames or lenses or ready-to-wear reading spectacles where multiple Master UDI-DIs have been assigned to the devices. Consequently, higher levels of packaging are most often to be considered as shipping containers for logistic purpose and should not have an assigned Master UDI-DI reflecting its contents.

In the event of a secondary packaging containing multiple devices (sale/trade items) with same assigned Master UDI-DI and corresponding to 1 sales unit, a Master UDI-DI may have to be assigned to the higher level of packaging other than device package to reflect its content.

5. Vigilance reporting for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

For spectacle frames, spectacle lenses and ready-to-wear reading spectacles as highly individualised devices, in case of vigilance reporting following a serious incident, the manufacturer should provide the UDI (Master UDI-DI + UDI-PI) of devices involved through the Manufacturer Incident Report (MIR) form (both when using a PDF MIR¹⁶ and the Eudamed Vigilance and Post-Market Surveillance module).

Since one Master UDI-DI encompasses a range of devices (group of devices) that can have multiple references, catalogue numbers and multiple PI's values, it is important that the manufacturer provide devices UDI (Master UDI-DI + UDI-PI) but also segregate more precisely, through its internal QMS/product traceability/product internal codification, devices involved in the serious incident reflected by at least one UDI (Master UDI-DI + UDI-PI) assignment.

Note: due to the timeline for the application of the Master UDI-DI assignment obligation, there is a possibility that spectacle frames, spectacle lenses and ready-to-wear reading spectacles may not yet be registered in the UDI/Devices Eudamed module when it becomes mandatory. When issuing entities Master UDI-DI codification standard will be fully available, manufacturers should engage with an issuing entity as soon as possible, and at least before the Vigilance and Post-Market Surveillance module of Eudamed becomes mandatory, in order to be able to assign Master UDI-DIs in due time and to handle the reporting of vigilance cases in Eudamed.

¹⁶ <https://ec.europa.eu/docsroom/documents/41681>.

6. Timeline for the assignment, application and Eudamed registration of device's Master UDI-DIs

Commission Delegated Regulation (EU) 2025/1920 on Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles was published in the *Official Journal of the European Union* (OJEU) on 23/09/2025 and entered into force on 13/10/2025. It applies from 01/11/2028, providing three-years transitional period as from its entry into force before the assignment of Master UDI-DI to spectacle frames, spectacle lenses and ready-to-wear reading spectacles labelling becomes mandatory.

The “MDCG 2025-7 Position Paper: Timelines of the implementation of ‘Master UDI-DI’ to contact lenses and spectacle frames, spectacle lenses and ready to wear reading spectacles”¹⁷ provides timeline clarification for highly individualised device (HID) manufacturers on Master UDI-DI assignment and device labelling requirement in regard to the Class I device requirements laid down in Article 123(f) MDR. Eudamed device registration for HID is also clarified against the Eudamed gradual roll-out timeline applicable to all medical devices other than HID.

Spectacle frames, spectacle lens, ready to wear reading spectacles produced prior to 1st of November 2028 are not required to have a Master UDI-DI on the label.

All this information is available on the section “Master UDI-DI for highly individualised devices” of the Commission webpage “Public Health > Medical Devices - Topics of Interest > Unique Device Identifier - UDI”¹⁸. More information is available in the Eudamed information centre¹⁹ and in the user guide²⁰ of the UDI/Devices Registration module of Eudamed²¹.

7. Annex

The Annex includes extended decision trees and additional infographic information on spectacle frames, spectacle lenses and ready-to-wear reading spectacles.

¹⁷ https://health.ec.europa.eu/document/download/ad6ae143-baa2-451a-8c5e-0c5d22983e88_en?filename=mdcg_2025-7_en.pdf.

¹⁸ https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en#master-udi-di-for-highly-individualised-devices.

¹⁹ <https://webgate.ec.europa.eu/eudamed-help/en/welcome-to-the-eudamed-information-centre.html>.

²⁰ <https://webgate.ec.europa.eu/eudamed-help/en/files/UDI%20Devices%20-%20user%20guide.pdf>.

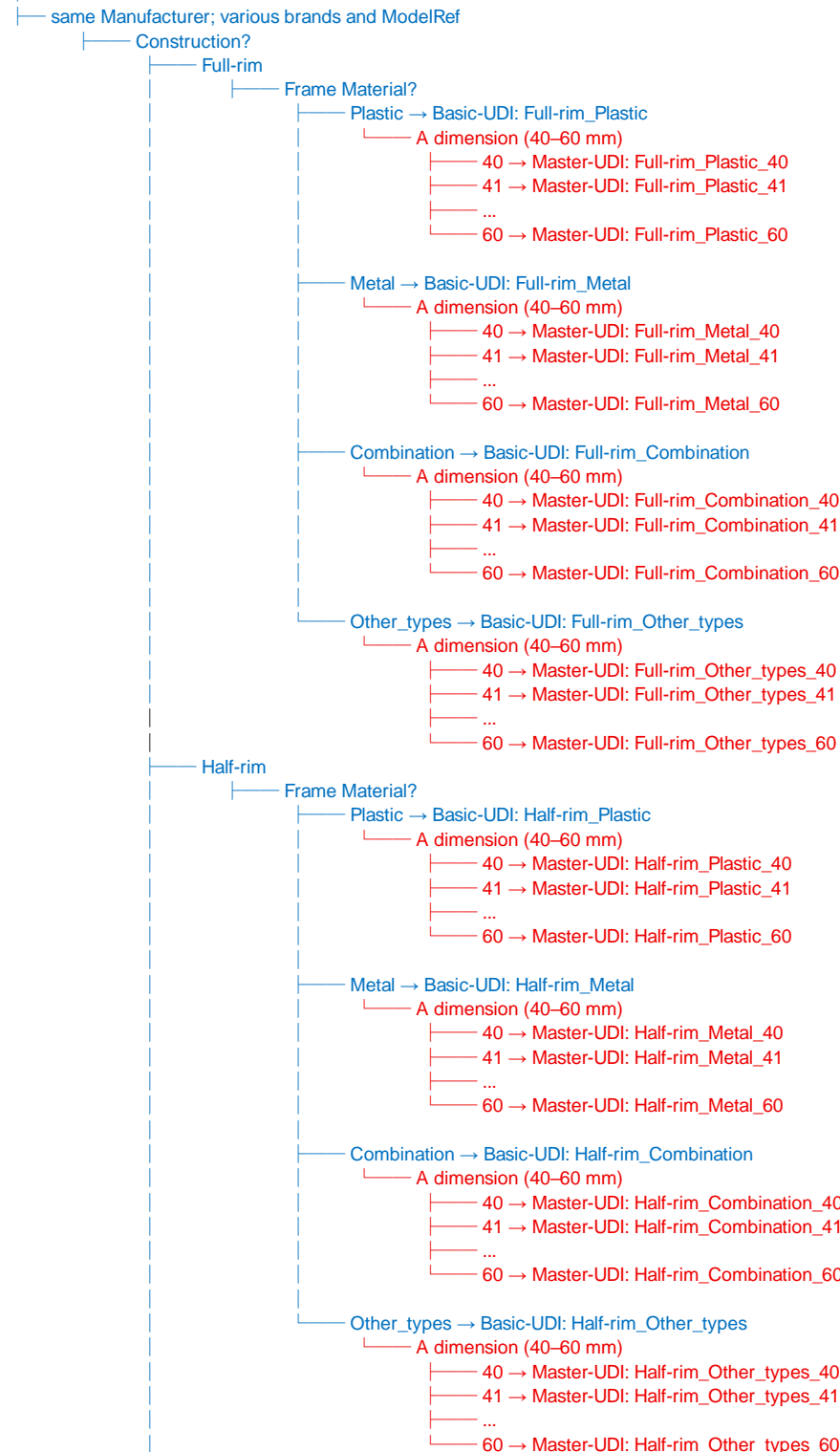
²¹ https://health.ec.europa.eu/medical-devices-eudamed/udiddevices-registration_en.

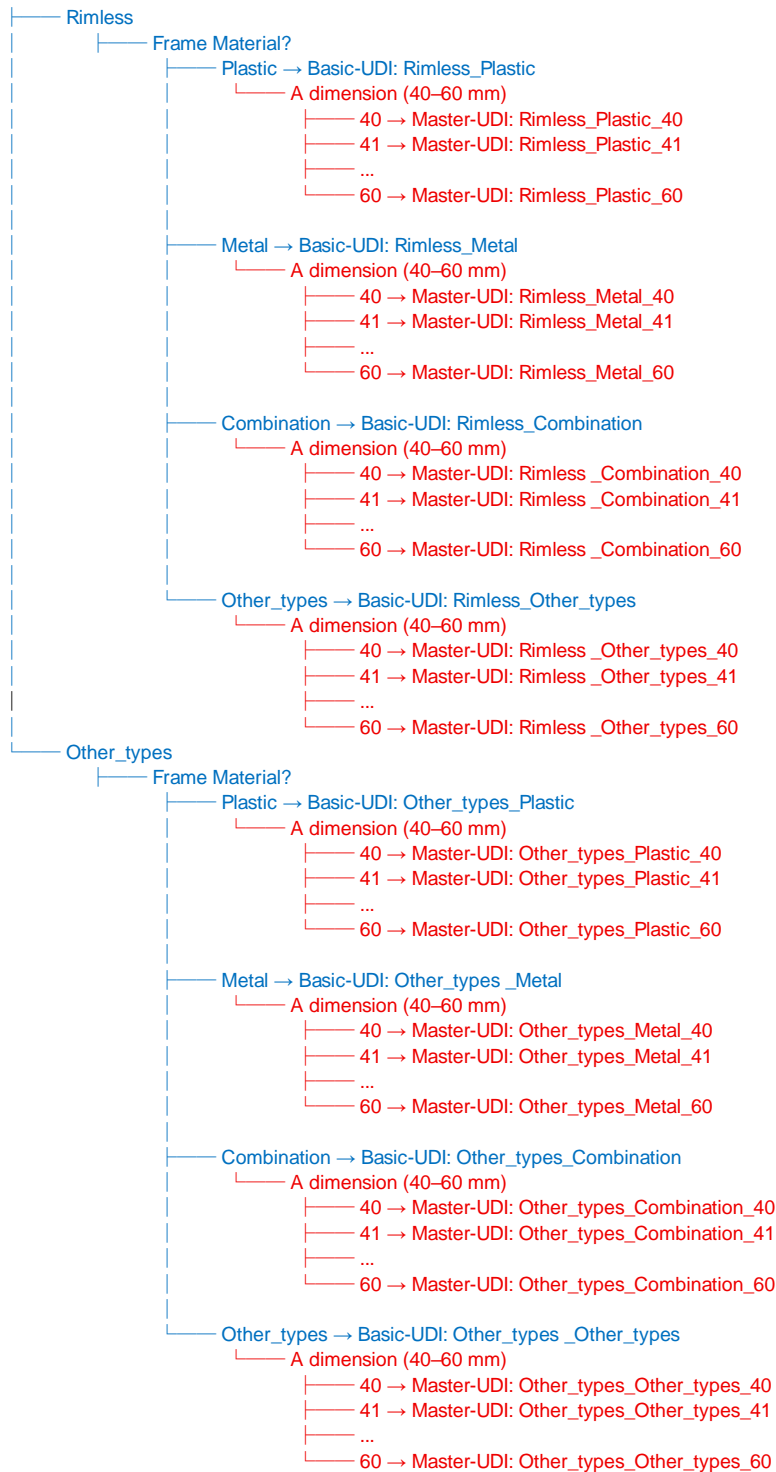
7.1 Spectacle frames – decision tree

Decision tree for spectacle frames including Basic UDI-DI and Master UDI-DI parameters:

Blue = Basic UDI-DI parameter, red = Master UDI-DI parameter

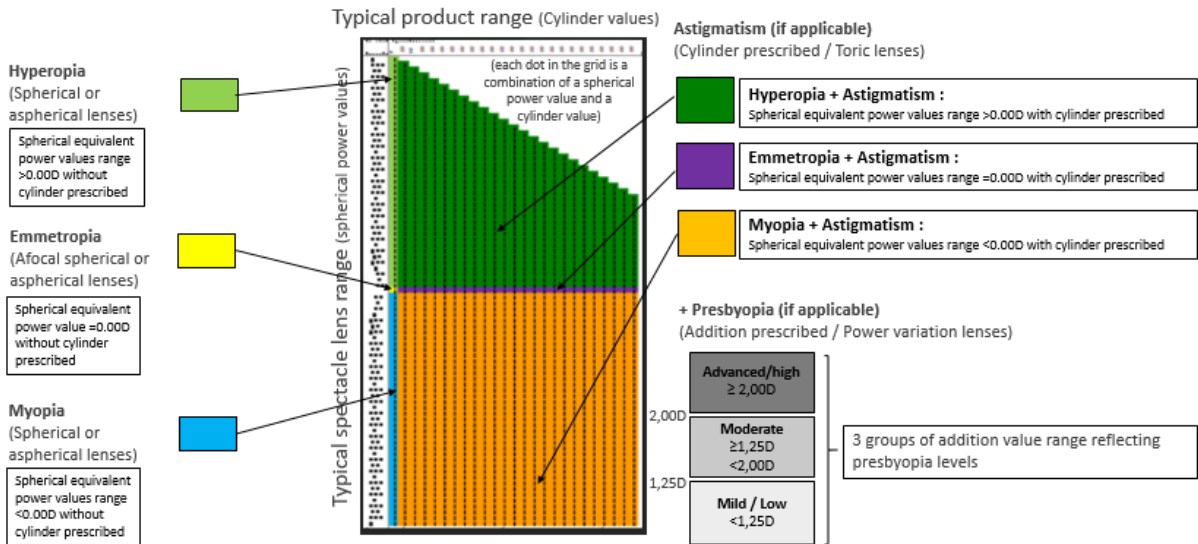
Start (spectacle frames)



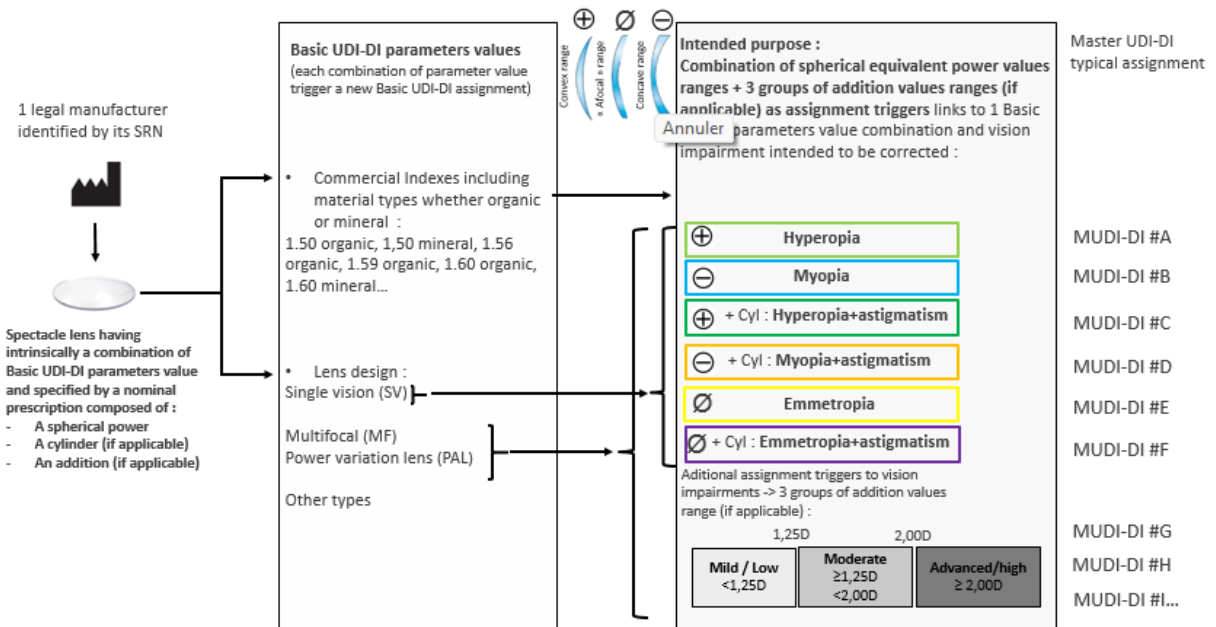


7.2 Spectacle lenses – additional infographic

Spectacle lenses typical range and vision impairments scheme:



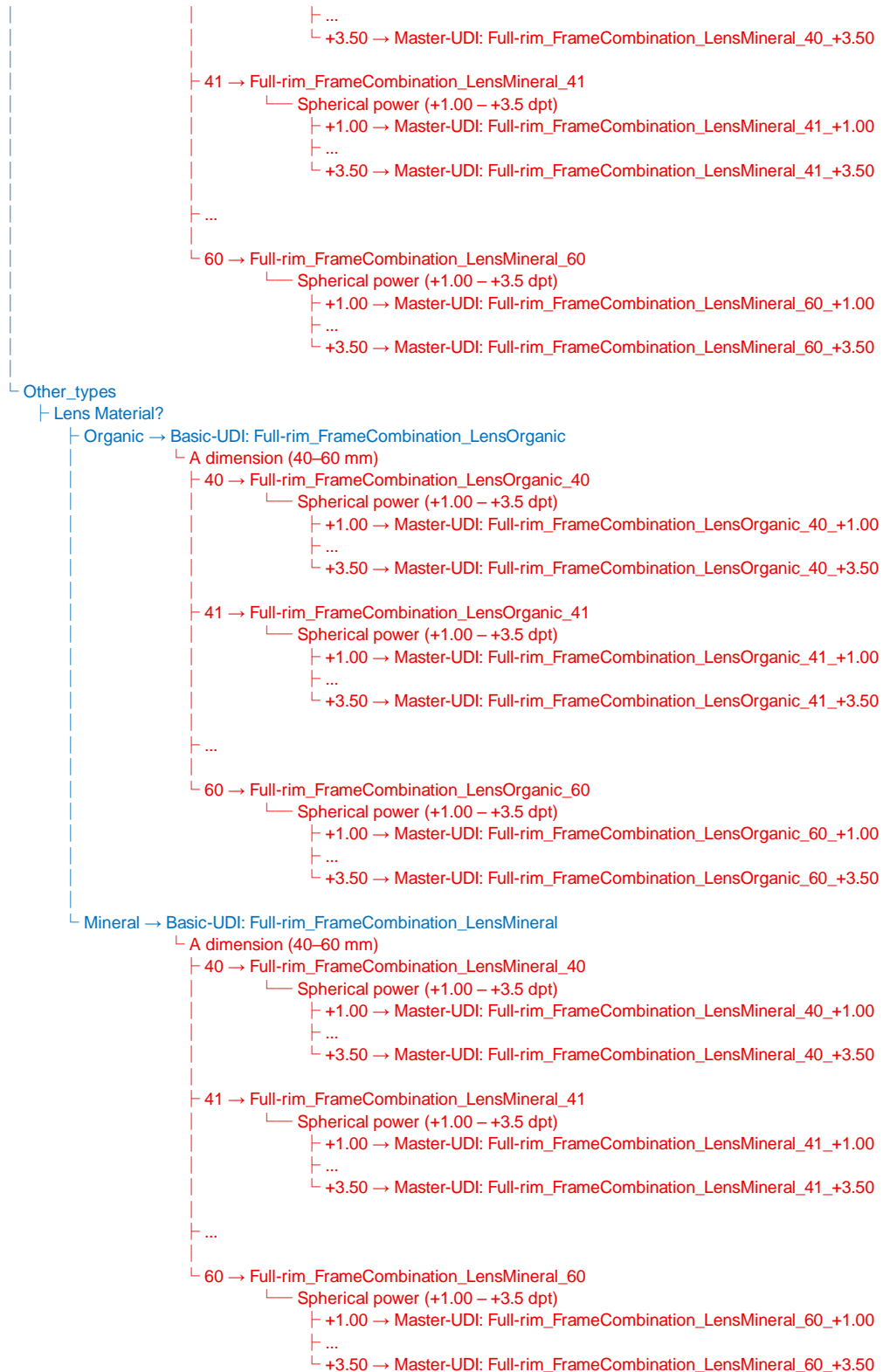
Global Master UDI-DI assignment scheme for spectacle lenses:

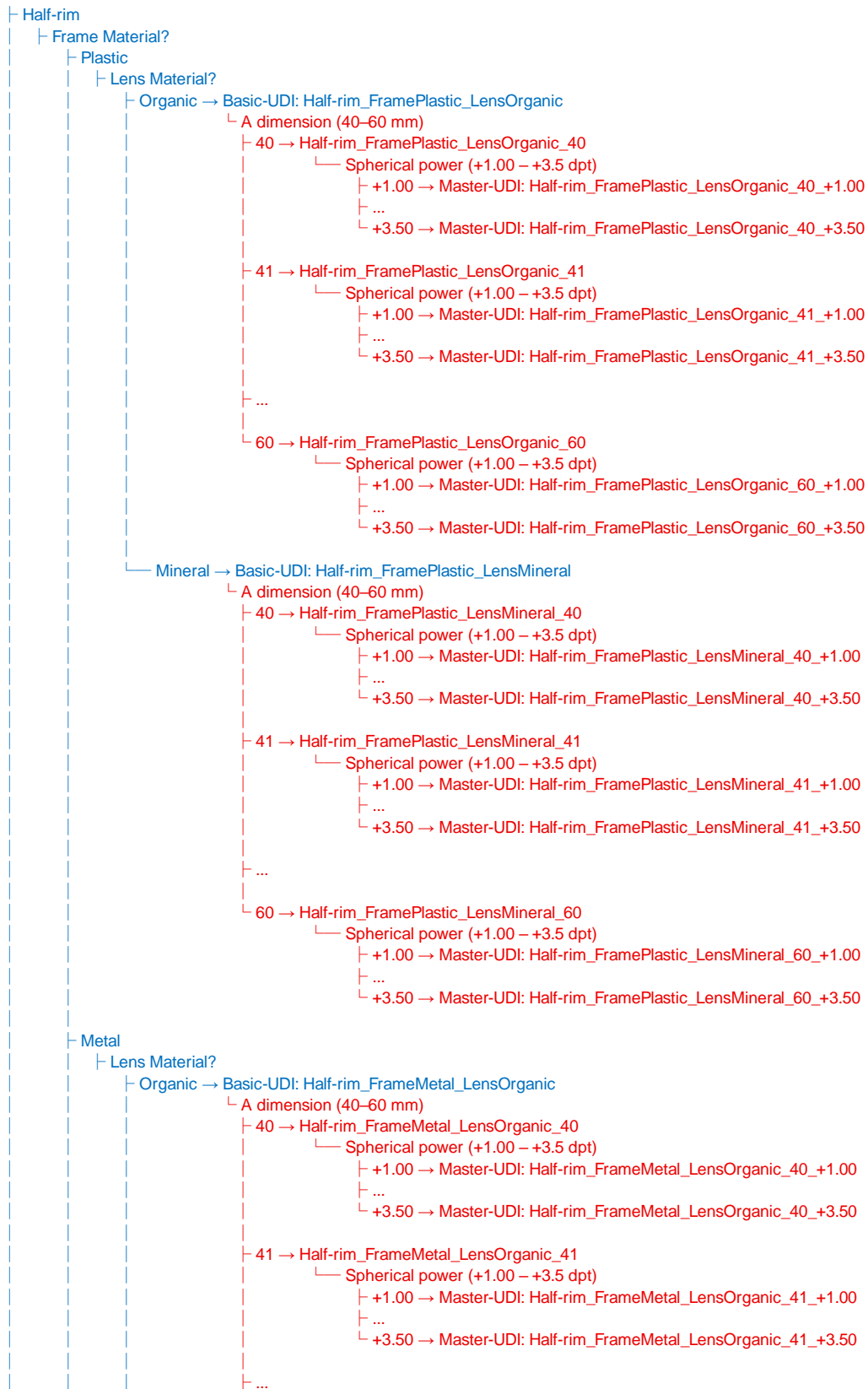


7.3 Ready-to-wear reading spectacles – decision tree

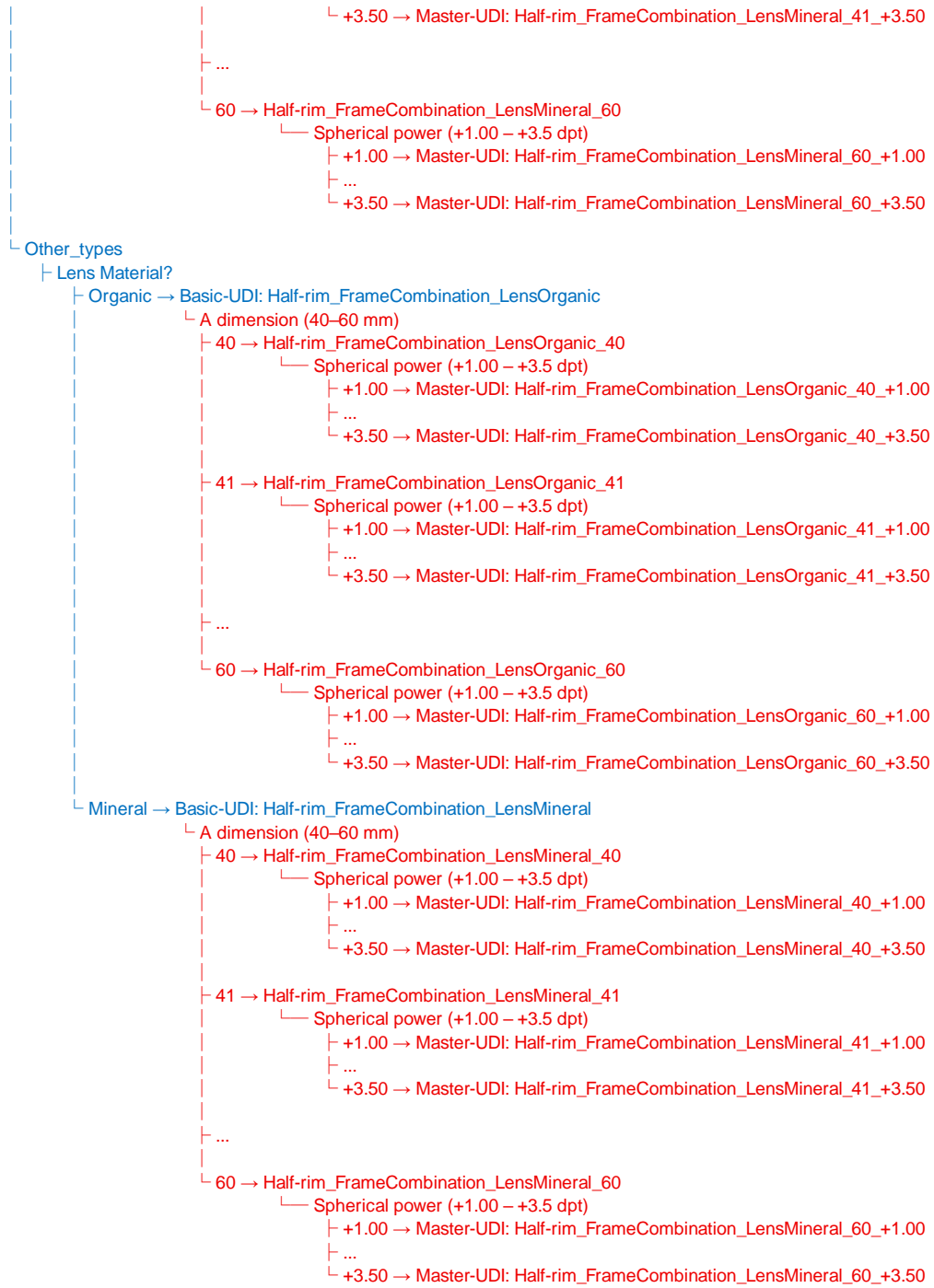
Decision tree for ready-to-wear reading spectacles including Basic UDI-DI and Master UDI-DI design parameters:

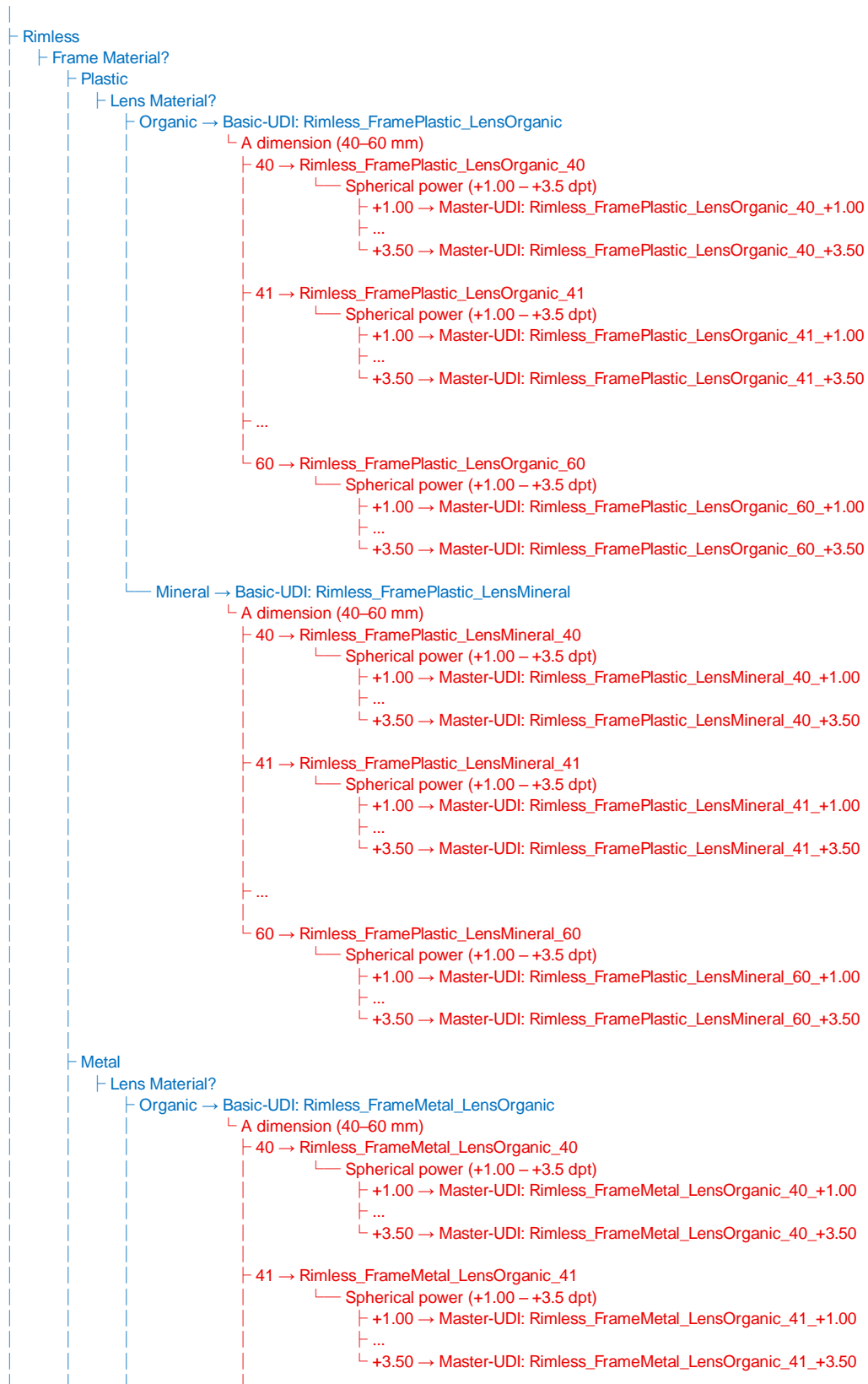
- └ 41 → Full-rim_FrameMetal_LensOrganic_41
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameMetal_LensOrganic_41_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameMetal_LensOrganic_41_+3.50
 - └ ...
 - └ 60 → Full-rim_FrameMetal_LensOrganic_60
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameMetal_LensOrganic_60_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameMetal_LensOrganic_60_+3.50
- └ Mineral → Basic-UDI: Full-rim_FrameMetal_LensMineral
 - └ A dimension (40–60 mm)
 - └ 40 → Full-rim_FrameMetal_LensMineral_40
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameMetal_LensMineral_40_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameMetal_LensMineral_40_+3.50
 - └ 41 → Full-rim_FrameMetal_LensMineral_41
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameMetal_LensMineral_41_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameMetal_LensMineral_41_+3.50
 - └ ...
 - └ 60 → Full-rim_FrameMetal_LensMineral_60
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameMetal_LensMineral_60_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameMetal_LensMineral_60_+3.50
- └ Combination
 - └ Lens Material?
 - └ Organic → Basic-UDI: Full-rim_FrameCombination_LensOrganic
 - └ A dimension (40–60 mm)
 - └ 40 → Full-rim_FrameCombination_LensOrganic_40
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameCombination_LensOrganic_40_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameCombination_LensOrganic_40_+3.50
 - └ 41 → Full-rim_FrameCombination_LensOrganic_41
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameCombination_LensOrganic_41_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameCombination_LensOrganic_41_+3.50
 - └ ...
 - └ 60 → Full-rim_FrameCombination_LensOrganic_60
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameCombination_LensOrganic_60_+1.00
 - └ ...
 - └ +3.50 → Master-UDI: Full-rim_FrameCombination_LensOrganic_60_+3.50
 - └ Mineral → Basic-UDI: Full-rim_FrameCombination_LensMineral
 - └ A dimension (40–60 mm)
 - └ 40 → Full-rim_FrameCombination_LensMineral_40
 - └ Spherical power (+1.00 – +3.5 dpt)
 - └ +1.00 → Master-UDI: Full-rim_FrameCombination_LensMineral_40_+1.00

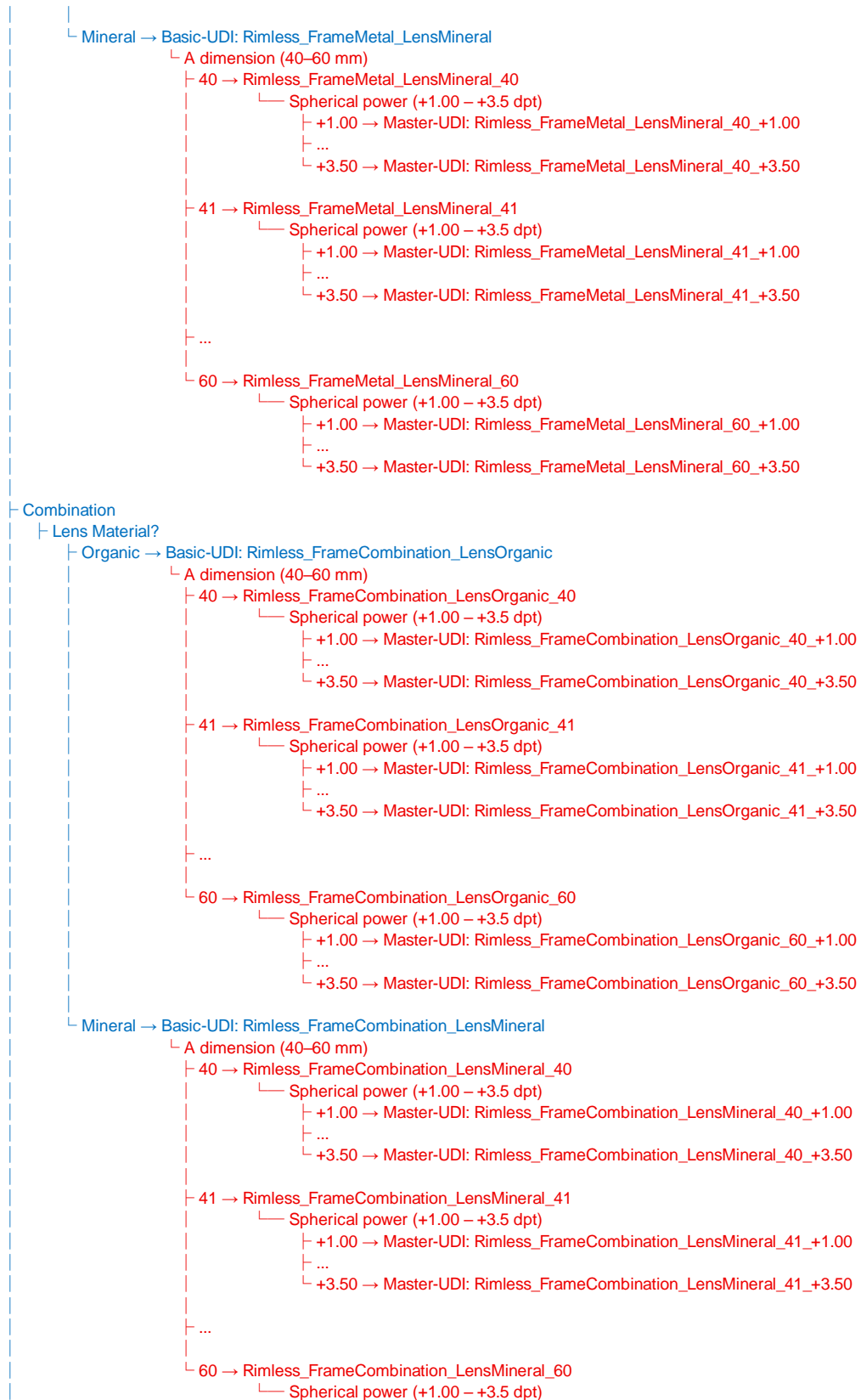


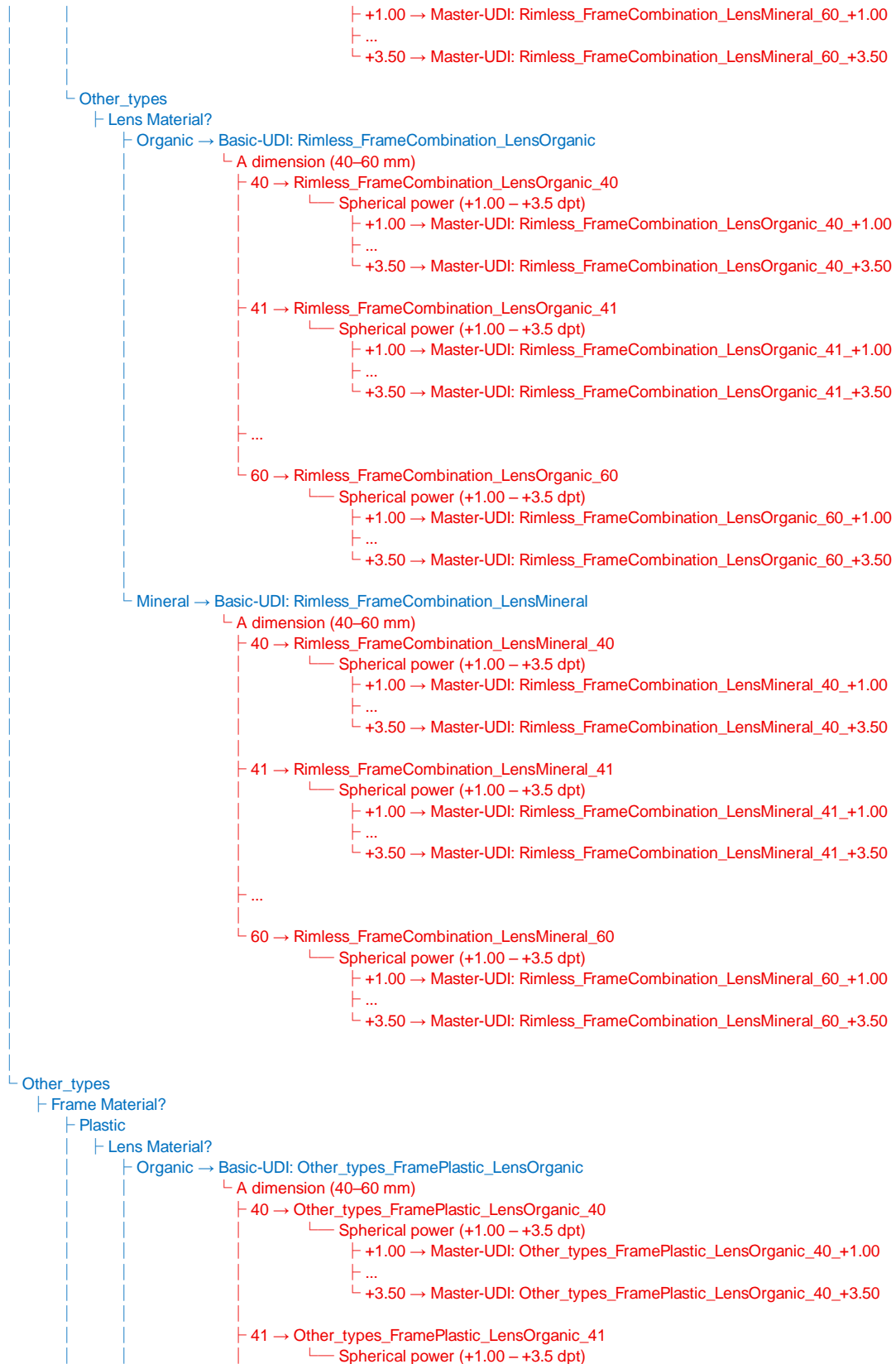


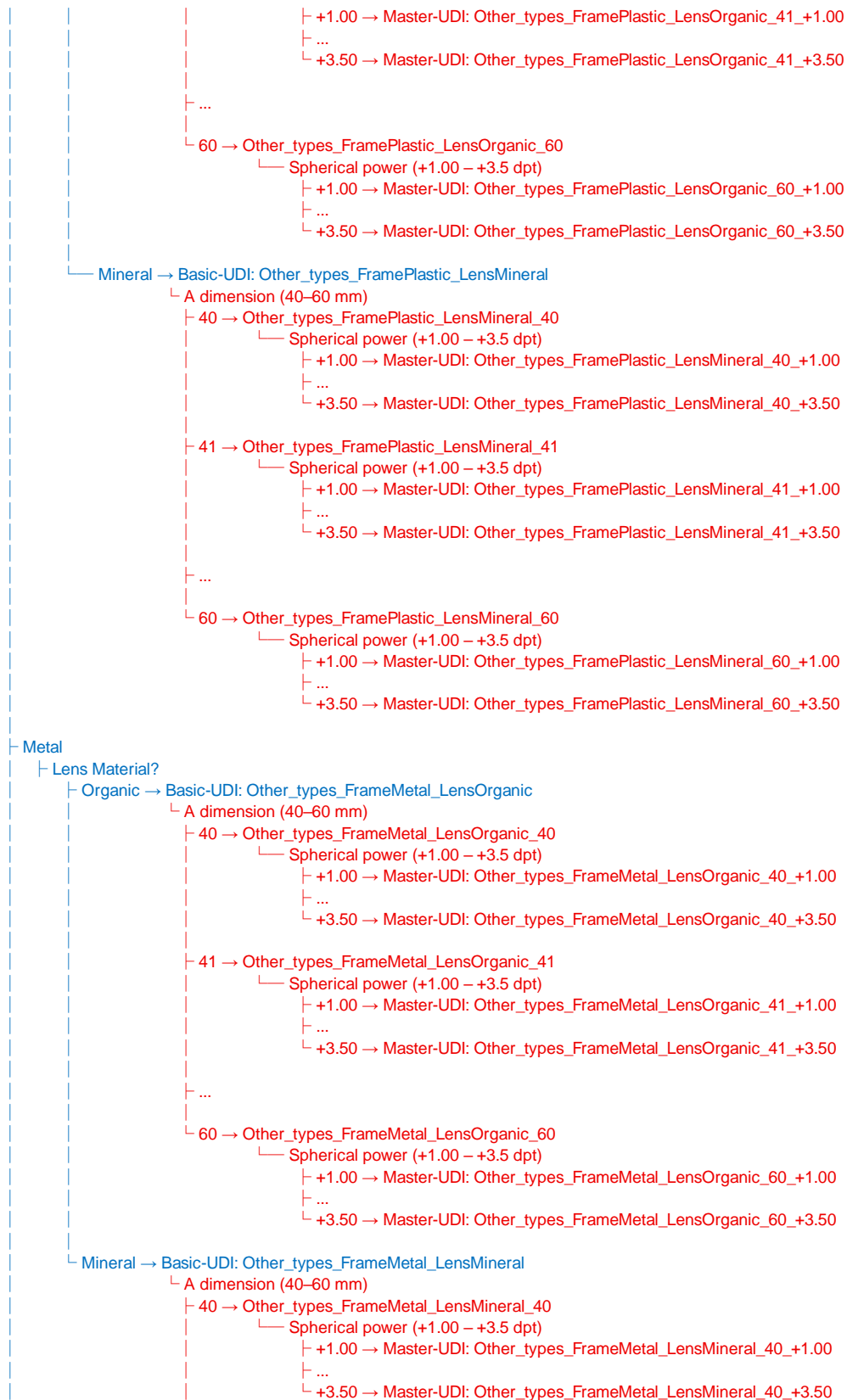
- └─ 60 → Half-rim_FrameMetal_LensOrganic_60
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameMetal_LensOrganic_60_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameMetal_LensOrganic_60_+3.50
- └─ Mineral → Basic-UDI: Half-rim_FrameMetal_LensMineral
 - └─ A dimension (40–60 mm)
 - └─ 40 → Half-rim_FrameMetal_LensMineral_40
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameMetal_LensMineral_40_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameMetal_LensMineral_40_+3.50
 - └─ 41 → Half-rim_FrameMetal_LensMineral_41
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameMetal_LensMineral_41_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameMetal_LensMineral_41_+3.50
 - └─ ...
 - └─ 60 → Half-rim_FrameMetal_LensMineral_60
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameMetal_LensMineral_60_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameMetal_LensMineral_60_+3.50
- └─ Combination
 - └─ Lens Material?
 - └─ Organic → Basic-UDI: Half-rim_FrameCombination_LensOrganic
 - └─ A dimension (40–60 mm)
 - └─ 40 → Half-rim_FrameCombination_LensOrganic_40
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameCombination_LensOrganic_40_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameCombination_LensOrganic_40_+3.50
 - └─ 41 → Half-rim_FrameCombination_LensOrganic_41
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameCombination_LensOrganic_41_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameCombination_LensOrganic_41_+3.50
 - └─ ...
 - └─ 60 → Half-rim_FrameCombination_LensOrganic_60
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameCombination_LensOrganic_60_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameCombination_LensOrganic_60_+3.50
 - └─ Mineral → Basic-UDI: Half-rim_FrameCombination_LensMineral
 - └─ A dimension (40–60 mm)
 - └─ 40 → Half-rim_FrameCombination_LensMineral_40
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameCombination_LensMineral_40_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Half-rim_FrameCombination_LensMineral_40_+3.50
 - └─ 41 → Half-rim_FrameCombination_LensMineral_41
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Half-rim_FrameCombination_LensMineral_41_+1.00
 - └─ ...

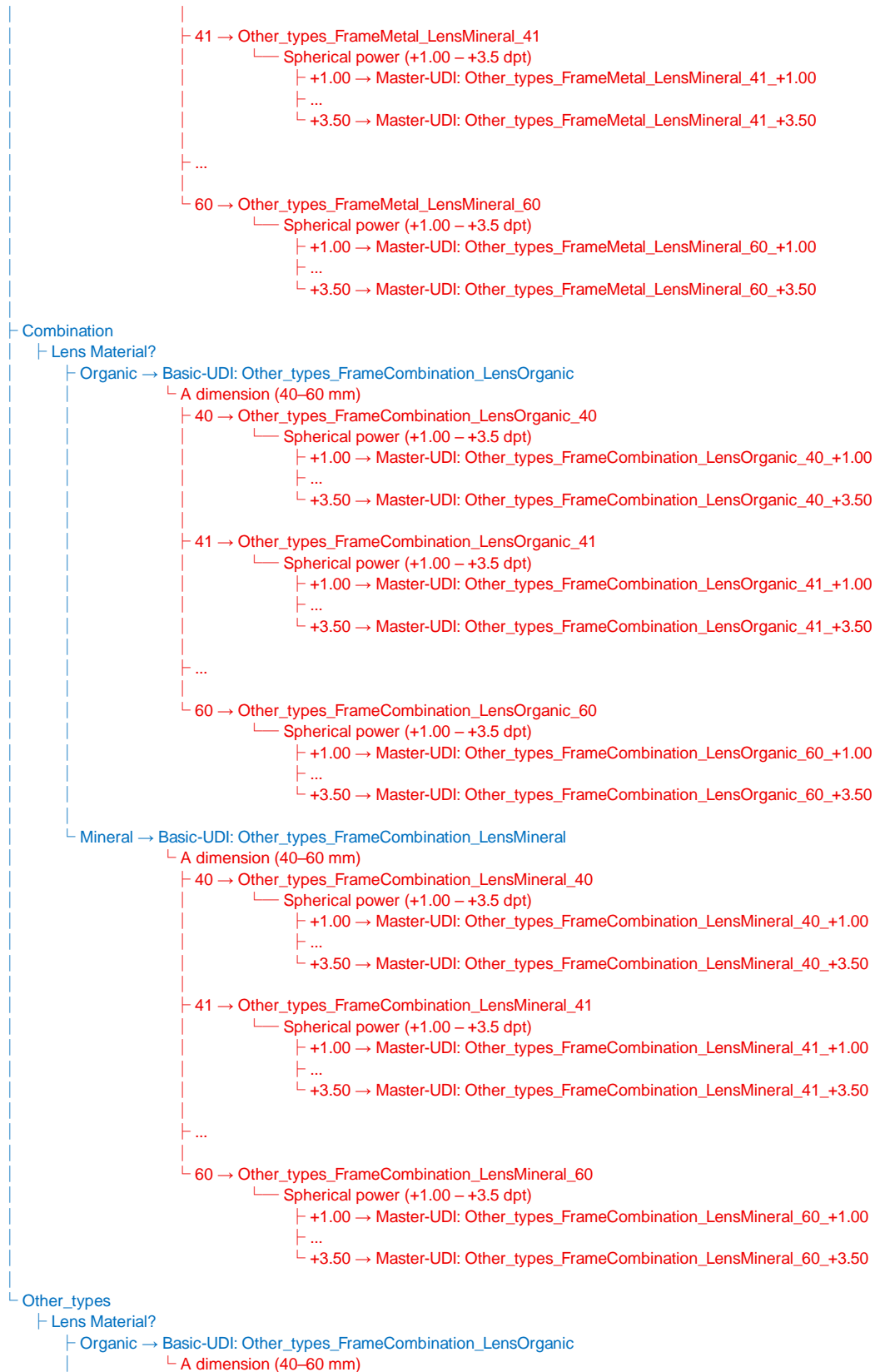












- └─ 40 → Other_types_FrameCombination_LensOrganic_40
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensOrganic_40_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensOrganic_40_+3.50
- └─ 41 → Other_types_FrameCombination_LensOrganic_41
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensOrganic_41_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensOrganic_41_+3.50
- └─ ...
- └─ 60 → Other_types_FrameCombination_LensOrganic_60
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensOrganic_60_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensOrganic_60_+3.50
- └─ Mineral → Basic-UDI: Other_types_FrameCombination_LensMineral
 - └─ A dimension (40–60 mm)
 - └─ 40 → Other_types_FrameCombination_LensMineral_40
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensMineral_40_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensMineral_40_+3.50
 - └─ 41 → Other_types_FrameCombination_LensMineral_41
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensMineral_41_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensMineral_41_+3.50
 - └─ ...
 - └─ 60 → Other_types_FrameCombination_LensMineral_60
 - └─ Spherical power (+1.00 – +3.5 dpt)
 - └─ +1.00 → Master-UDI: Other_types_FrameCombination_LensMineral_60_+1.00
 - └─ ...
 - └─ +3.50 → Master-UDI: Other_types_FrameCombination_LensMineral_60_+3.50