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

EuromContact
Avenue des Arts 56
1000 Bruxelles
BELGIUM

Kristina Kübar
Health Board

Brussels, 21 February 2023

***Subject**: Proposals for the upcoming Commission Delegated Regulation on Unique Device Identification (UDI) assignment criteria for highly individualised medical devices (contact lenses)*

EUROMCONTACT represents the European manufacturers of contact lenses and lens care solutions. EUROMCONTACT represents 90% of the soft contact lenses and 50% of the rigid or made-to-order contact lenses distributed in the EU market.

In the implementation framework of the Medical Device Regulation 2017/745, specifically obligations relating to the UDI system and registration, the European Commission has determined that for contact lenses:

- Due to the large number of device permutations for contact lenses, a large number of records would be required in EUDAMED under the existing regulation.
- To reduce the risk of disproportionate UDI-DI data entries in EUDAMED database, a "Master UDI-DI" solution is required for contact lenses, which will group devices to reduce the number of entries.
- Clinical size information is to be encoded with Master UDI-DI as Production Identifiers on the UDI label as the specific clinical size device information will be lost with the proposed Master UDI-DI solution.

EUROMCONTACT is convinced that genuine solutions can be achieved to ensure effective traceability of contact lens devices and improved patient information, while considering operational constraints, patient safety and the legal framework.

EUROMCONTACT therefore supports the following positions:

- **Standard Contact Lenses**
    - For standard contact lenses, **utilization of existing UDI-DI assignment is still the best solution** to address all benefits of the UDI system.
    - The **number of UDI-DI records for standard contact lenses is not a technical limit** and will not create an issue with appropriate database design to sort/filter records.

- **Made to order (MTO)**

Made to order (MTO) contact lenses are not suited to use the existing UDI-DI scheme used for standard lenses due to more than 1 million of combination of parameters available by lens design model. **Therefore, the industry proposes to group MTO contact lenses with common characteristics.**

- **Clinical Sizes**

However, addition of clinical size data to the UDI-PI portion of the label for standard and MTO lenses does not provide the perceived benefit, and further to this, it places a disproportionate burden on manufacturers. For these reasons, **Euromcontact members strongly urge the Commission to not pursue the proposed addition of clinical sizes to the UDI of contact lenses**.

Further information on these points have been explained in the **Annex document** to this letter.

We look forward to continuing to partner in good spirit with the EU Commission and Competent Authorities to find an amicable solution for all participants.

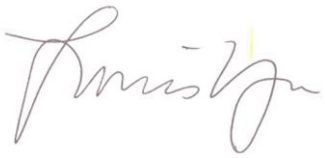
Yours sincerely,

Gianluca Gallinotti
VP VC Europe
Alcon

Dr. Louis Yu
Chief Quality Officer
Bausch & Lomb

Jerry Warner
EVP, President
CooperVision

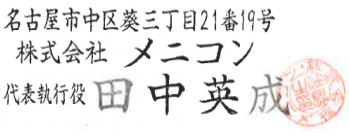
Marion Beeler-Kaupke
Executive Director
EFCLIN

Jacqueline Henderson
Area V.P. EMEA
Johnson & Johnson Vision Care, Inc.

Cristian E. Ostrowski
CEO
Mark'ennovy Personalized Care

Menicon



Master UDI-DI in context of EU MDR Regulation 2017/745 – Background

As declared in the introduction of Medical Device Regulation, the aim of the Regulation is to provide a robust, transparent, predictable and sustainable regulatory framework for medical devices[1] in a way in which provides a harmonized approach[2] for all devices. This introduction also includes the aim to provide alignment, in particular to the IMDRF, to the extent possible, in order to promote global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations[2]. The goal of the UDI system is to ensure the traceability of devices for all parties, with the objective of the database to enhance overall transparency, including through better access to information for the public and healthcare professionals[3]. The UDI system should apply to all devices placed on the market, be based on internationally recognised principles, significantly enhance the effectiveness of the post-market safety-related activities, help to reduce medical errors, as well as many other benefits listed in the Medical Device Regulation[3].

Article 27 of the Medical Device Regulation outlines the UDI system obligations, clearly stating that the UDI-DI provides access to the information laid down in the UDI database referenced in Article 28 (known as EUDAMED).

The Medical Device Regulation UDI labelling requirements[4] are in close alignment with the International Standards set out by the IMDRF for UDI[5], whereby all medical devices are to assign a UDI, comprising of a UDI-DI and a UDI-PI.

The UDI-DI for contact lenses, is assigned at the lowest level of granularity to ensure it provides the necessary level of traceability to a 'specific to a model of device'[6]. Because of the number of clinical size types and the large number of clinical sizes for these types, this results in a large volume UDI-DI's being assigned for a given contact lens design.

Master UDI-DI in context of EU MDR Regulation 2017/745 – Challenges

This volumetric challenge was acknowledged by the US FDA prior to their implementation of the GUDID database, and they issued a letter on 30th March 2017 granting an extension to comply with the UDI system requirements for 'Soft Contact Lens Labelers'.

The EU Commission also acknowledged this challenge for the EUDAMED system, and the following actions were taken:

1. The challenge was raised at the MDCG UDI and EUDAMED working groups where EUROMCONTACT have been actively involved since the beginning.

[1]MDR 2017/745 Introduction (1)
[2]MDR 2017/745 Introduction (5)
[3]MDR 2017/745 Introduction (41)-(44)
4 MDR 2017/745 Annex VI Part C
[5] IMDRF/UDI WG/N48 FINAL:2019 – UDI System Application Guide
[6]The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

2. In May 2021, MDCG 2021-09 guidance was published highlighting that specific UDI assignment solutions would be defined for contact lenses[7].
3. In August 2021, the EUCOM issued a work request to GS1 to develop a solution for a 'Master UDI' for contact lenses[8].

Master UDI-DI in context of EU MDR Regulation 2017/745 – Master UDI-DI assignment solution development

On 14th October 2021, there was a call to action from GS1 and a working group was formed between industry, the EU Commission, and GS1. In these working groups there is active participation from all groups in the spirit of finding a proportionate solution. As the working groups progressed, Master UDI-DI solutioning was further reviewed and developed as an appropriate solution to the request to reduce the number of EUDAMED entries for contact lenses as identified by the Commission. Refer to Figure 1 for a detailed view on the UDI hierarchy and where Master UDI-DI fits in.

The addition of the specific clinical sizes for the contact lens was also discussed as a requirement on the UDI barcode, and it was the understanding from the industry that this was not required to satisfy the primary requirement of being able to register contact lens information in EUDAMED. Subsequently this was not included in earlier versions of the Business Requirement Analysis Documents (BRAD) published by GS1 (output from the working group meetings).

The members of EUROMCONTACT provided key input and engaged in the development of the Master UDI-DI concept and on 6th June 2022, a letter was sent to the EU Commission indicating the time estimate it would take the industry to implement the Master UDI-DI requirements. This letter was produced in good spirit to help the EU Commission apply the appropriate transition timeframes for the proposed delegated act[9].

Master UDI-DI in context of EU MDR Regulation 2017/745 – Recent developments Q3/Q4 2022

In more recent GS1 Master UDI-DI working group meetings, the EU Commission added the requirements to include encoding the clinical size of the contact lens within the UDI barcode along with the Master UDI.

Industry asked why the clinical size of the contact lenses needed to be encoded within the UDI barcode along with the Master UDI, and on the 22nd September 2022 a call was held between the regulators (Belgium, Germany and Sweden), the EU Commission and the industry to clarify this.

1. It was explained that because the exact clinical size information would not be available in EUDAMED for the patient (because information is stored at the Master UDI-DI level, and thus only the clinical size ranges would be available), that the exact clinical size needs to be encoded on the UDI barcode.
2. It was also confirmed that this would be required on the scan result of the UDI Automatic identification and data capture (AIDC) barcode, and if there were space constraints the human readable interpretation (HRI) of the clinical size information would not be required.
3. Further, it was communicated that the Master UDI-DI would replace the UDI-DI requirements for contact lens devices. Therefore, Master UDIs would require further granularity and no UDI-DI assignment for individual contact lens devices would be required.

[7]MDCG 2021-09 MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers. May 2021
[8] WR-21-000283 - New EU requirements for medical devices identification (i.e. Master UDI-DI) MSWG
[9] Commission Delegated Regulation on UDI assignment criteria for highly individualised devices (contact lenses)

Master UDI-DI in context of EU MDR Regulation 2017/745 – Trade Association Concerns

1. **Change in use case**
   a. The industry was working toward a proportionate solution with the EU Commission and GS1 to solve for the volumetric problem of having too many entries in EUDAMED for contact lens products.
   b. The use case for the patient to scan a barcode to retrieve device information was not communicated as a need to the GS1 working group until the 22nd September 2022 meeting.

2. **Prevalence /Practicality ('edge case')**
   a. The use case for the patient to scan a barcode to retrieve contact lens size information is not prevalent over consumers using current methods of referencing the device labelling or accompanying documentation in the case of Made To Order (MTO) lenses (see Figure 2).
   b. **The clinical size information is available in an easy-to-read format for the patient and health care provider currently via labelling and accompanying documentation.** The use case of retrieving data via the barcoding would require the user to download the necessary application to read the barcode, scan it and correctly interpret the results in a GS1 scan result (see Figure 3). This decoded data would not correspond to the format of the patient's prescription.

3. **Unfit for purpose**
   a. The EU Commission have highlighted only needing to encode up to 4 clinical sizes for the contact lens within the UDI barcode along with the Master UDI. Standard contact lenses have often more than 4 clinical sizes and in the case of MTO lenses, there can be many more clinical sizes. 4 clinical sizes do not uniquely describe the entirety of the lens and adds **additional risk for miss-identification**.
   b. The UDI is not designed or intended to hold a large quantity of information. Therefore, encoding clinical sizes in addition to the other UDI elements (including Master UDI) is **not practicable**.
   c. The UDI barcode scan results containing these additional data strings are **not designed for human readable** consumption, as is demonstrated by the system format example seen in Figure 4.
   d. Most MTO manufacturers are awaiting the outcome of the discussions since current solutions are not fit for purpose.
   e. Adding the clinical size within the UDI barcode would not aid the vigilance activities, as clinical size capture is not required as part of this process to uniquely identify the device in the marketplace. With the solution proposed, clinical size data will still not be in EUDAMED. This will have an impact on any trending and signal detection of issues in the field as it will be difficult to determine any issues with a specific clinical size. Traceability of issues across markets will be lost as all other markets are utilizing the UDI-DI for standard contact lenses. **The clinical size design actually provides less traceability** rather than more for everyone concerned.

4. **Article's 27, 28 and 29 of the Medical Device Regulation are fit for purpose**
   a. EUDAMED has been developed as a key source for users to gain device information, including pack size and clinical size information.
   b. Separate UDI-DIs are assigned for each clinical size of a contact lens. UDI-DI has already been implemented by all standard contact lens manufacturers for Global UDI requirements.

5. **Conflicts with Global UDI Regulations**
    a. The following markets are accepting a UDI-DI upload of contact lens information in the UDI Registration database:
        i. Active UDI Registration markets: South Korea, China, Saudi Arabia
        ii. Published UDI Registration Regulation not active: Brazil, Columbia, Australia, Japan, Taiwan, Singapore, Egypt
    b. Currently there are **no other Health Authorities** proposing:
        i. the requirement for a Master UDI-DI and clinical size encoding for contact lenses within UDI barcode;
        ii. the requirement to register contact lens UDI information at the Master UDI-DI level.
    c. In a meeting held on 6th October 2022 between Contact Lens Institute (US Contact Lens Trade Association) and the US FDA, the US FDA acknowledged the complexity presented by the Master UDI-DI proposal, and that the volume of data loading at the UDI-DI level for contact lenses does not pose a technical volumetric issue to GUDID.

6. **Conflict with Global UDI Standard Harmonisation**
    a. The solution proposal for the Clinical Size information to be encoded in the UDI barcode is as a set UDI Production Identifiers (UDI-PI). The Medical Device Regulation defines UDI-PI as 'The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production'. This definition aligns with the IMDRF[12].
    b. The Clinical Size information for a contact lens does not identify the unit of device production.
    c. IMDRF documentation[10] indicates the contents of the labelling that shall appear in UDI Database not the UDI Barcode. Clinical size information is on the device labelling and therefore should be in EUDAMED. Further to this the Medical Device Regulation currently aligns with this standard by stating clinical sizes are to be captured in the UDI Database (EUDAMED)[11]. **Utilizing the Master UDI-DI will not allow sufficient granularity for these items required to be reported in EUDAMED**.

7. **Limited Space (Constraints on packaging)**
    Contact lenses are small devices, as such the Sterile Barrier and outer packaging is space constrained. The Master UDI-DI solution with Clinical Size information **compromises the position and prominence of other critical labelling information**. This results in having to have the same contact lens being packaged in multiple configurations for the EU e.g., to allow for the various language translations.

8. **Conflicts with another EU initiatives/argumentation**
    The EU Commission has indicated to the contact lens industry the need for a physical copy of the Instructions For Use (IFU) to be supplied with the device to the end user. This requirement is based on the reasonable assumption that all patients do not have the capability to scan a QR code to retrieve the IFU electronically as proposed by the industry.
        i. The solution for Master UDI-DI assumes that patients do have scanning capability.
        ii. There is a contradiction in argumentation for requirements by the EU Commission.

[10] IMDRF/WG UDI/N7Final:2013
[11] Annex VI Part B, Paragraph 12: The manufacturer shall provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device: 12. if applicable, clinical size (including volume, length, gauge, diameter),

9. **Traceability**
    a. By applying the Master UDI-DI to contact lenses, the solution does not align with the rest of the global medical device industry, including the global contact lens device industry. This lack of alignment increases complexity in global supply chain systems from manufacturing all the way through to retailers as multiple levels of identification and barcode variations require accommodation and ability to track /link vigilance events across markets will be lost.
    b. By introducing a higher level of identification for contact lenses, without the UDI-DI level of traceability for contact lenses within the EUDAMED database:
        i. There is an **increased risk of 'copycat' counterfeit devices** entering the marketplace for standard contact lenses, as UDI-DI assignment provides the individual device identification.
        ii. The higher level of identification **does not improve patient safety** and only **adds complexity when trying to find specific device information**.
    c. Stakeholders will not be able to use the UDI-DI specific to a model of device, as the 'access key' to information stored in the UDI database.[12]
    d. Listing of individual devices associated with a certificate will not be publicly available and only the manufacturer will have a record of the devices. This **undermines a core principle of the system** as noted on the EUDAMED website: EUDAMED improves transparency and coordination of information regarding medical devices available on the EU market.[13]

Master UDI-DI in context of EU MDR Regulation 2017/745 – Disproportionate Solution

Based on all the concerns above, it is the opinion of EUROMCONTACT that the current solution being proposed by the EU Commission incurs a disproportionate burden on the entire contact lens supply chain over the proposed prevalence and benefit and will require:

1. **Manufacturers**
    a. Establishment of an additional source of record for Master UDI-DI and all related processes and procedures in addition to already implemented UDI-DI processes for Global Harmonisation and existing supply chain and distribution requirements.
    b. Modifications / proliferations of packaging artwork variations to accommodate the required increased AIDC / HRI space.
    c. Additional systematic processes will need to be established:
        i. To feed Master UDI-DI to manufacturing and packaging systems.
        ii. To change scanning systems to accommodate an increased scan result length, with changes to parsing rules, between manufacturing, packaging and distribution sites globally.
    d. Manufacturing downtime globally for implementing and testing changes.
    e. Degradation of current manufacturing capacity due to increased variable printing times resulting in having to build additional capacity (see Figure 6). The additional cost of building this capacity will be passed onto the consumer.
    f. Increased customer communications and vigilance case increases.
    g. Managing bifurcated processes for UDI across:
        i. UDI Registration:
            - EUDAMED registration process being different to Global UDI registration for contact lens manufacturers.

[12]MDR 2017/745 Annex VI, Part C, 1. Definition UDI-DI
[13]EU Commission, EUDAMED Overview (Overview (europa.eu)); Accessed November 9, 2022

- For device manufacturers that produce contact lenses and other devices, they will have 2 different methods of device registration to manage for the EU.

ii. UDI Labelling – Additional EU requirements

h. Global Registration Impact:
   i. For global items shared with the EU, notifications will be required
   ii. Post notification inventory management is required in regions which do not allow mixed labelling

2. Distributors / Retailers

Additional systematic requirements will need to be established to change scanning systems to accommodate an increased scan result length, with changes to parsing rules, between distributors and retailers globally.

3. Patients and Health Care Providers

a. An extensive outreach would need to be made to educate Health Care Providers and patients, on how to do things differently for contact lenses versus all other devices.
b. Furthermore, the 2D Datamatrix barcodes cannot currently be read natively by smartphones. The user would need to identify which app(s) to download, some of which may not be available free of charge thus engendering unwanted and unnecessary cost to a patient. There is also the risk of the patient downloading a malevolent app.

Master UDI-DI in context of EU MDR Regulation 2017/745 – Conclusion

In summary, the current proposed solution places a disproportionate burden on the global contact lens industry supply chain against the proposed perceived benefit gained from patient being able to scan the UDI barcode to retrieve the Master UDI-DI and Clinical Size information for the contact lens. As demonstrated above it is also not in alignment with the purpose and intent of the UDI requirements as written in the Medical Device Regulation.

Master UDI-DI in context of EU MDR Regulation 2017/745 – EUROMCONTACT Recommendations

1. MTO Contact Lenses

The industry proposes to **group MTO contact lenses with common characteristics.** EUROMCONTACT proposes to assign to each MTO contact lens model a UDI-DI defined by **lens material, geometry and package quantity**, to allow the registration in EUDAMED and labelling (example in Figure 7).
To use clinical size within the grouping for MTO Contact Lenses would not be feasible due to the custom nature of these lenses (more than one million combinations).

2. Standard Contact Lenses

Recommended approach : adopt UDI-DI as written in MDR 2017/745

EUROMCONTACT welcomes the EU Commission and Competent Authorities to **reconsider leveraging the UDI regulation as written in the Medical Device Regulation**. We acknowledge the volumetric challenges faced by the EU Commission within EUDAMED of this approach, however this allows for alignment benefits highlighted in this document including harmonisation with all other standard medical devices in the EU, traceability, Global Harmonisation, and ease of adoption. EUROMCONTACT is willing to partner with the EU Commission and Competent Authorities to support the delivery of this solution.

Alternative – Adopt Master UDI-DI assignment within UDI-PI

Should the EU Commission wish to proceed with adopting the Master UDI-DI concept, the Master UDI-DI can be included in the UDI barcode within a specific PI to enable EUDAMED registration, however the GTIN, for example, would remain the primary identifier at each pack level and clinical size.

3. Clinical size information associated to Master UDI-DI

EUROMCONTACT urges the EU Commission and Competent Authorities not to include Clinical Size encoding within the UDI barcode as part of this solution. This is due to the disproportionate burden it places on the entire Global Contact Lens supply chain with no patient benefit.

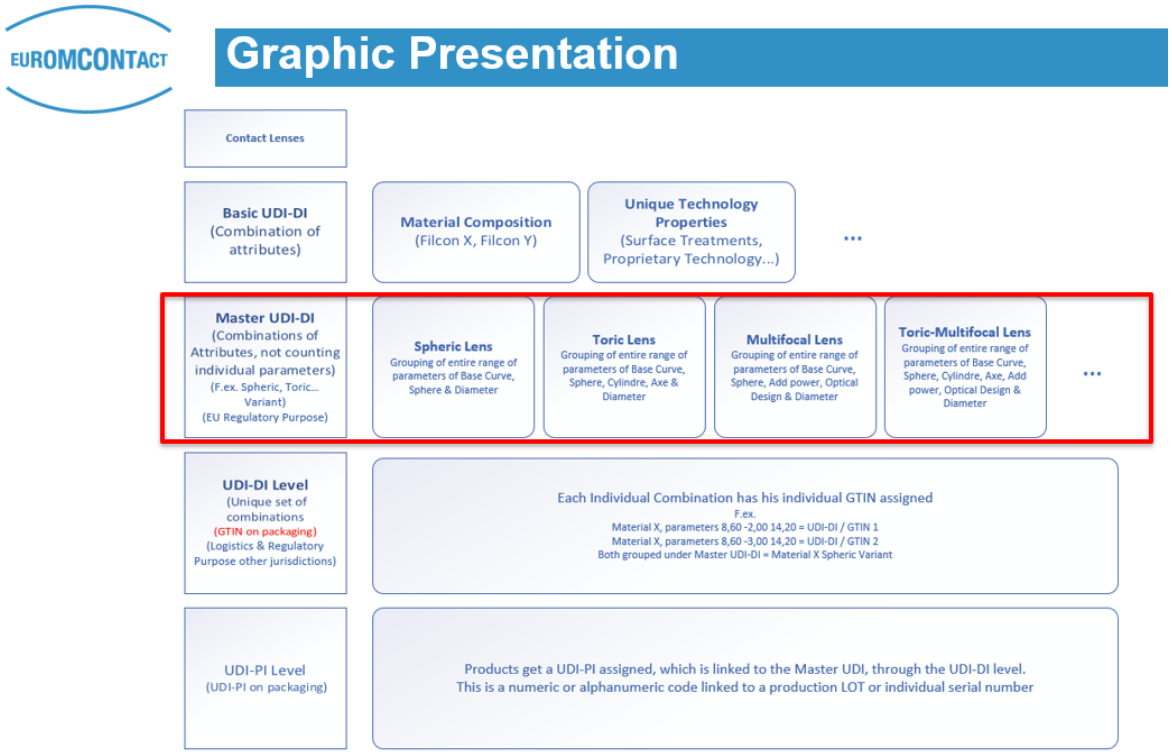
(*applicable only to Standard Contact Lens alternative option*)

EUROMCONTACT suggests if there is a requirement for the clinical size of each contact lens within the Master UDI-DI group to be transparent within the UDI framework, that EUDAMED is updated to allow manufacturers to upload a document (e.g., PDF or CSV) of all associated pack and clinical sizes for a Master UDI-DI (including UDI-DIs for standard lenses). This can be made available in the EUDAMED system for users to download for a Master UDI-DI grouping, and the necessary obligations can be placed on the manufacturer to maintain this uploaded document.

ABOUT EUROMCONTACT

EUROMCONTACT is the voice of the European contact lens and lens care industry to the European Institutions, media, stakeholders and the public. EUROMCONTACT members include national associations of manufacturers representing Belgium, Finland, Germany, Italy, Netherlands, Spain, Switzerland and the United Kingdom; the global companies Alcon, Bausch & Lomb, CooperVision, Johnson & Johnson Vision, Mark'ennovy, Menicon and Avizor; and the European Federation for the Contact Lens Industry EFCLIN.

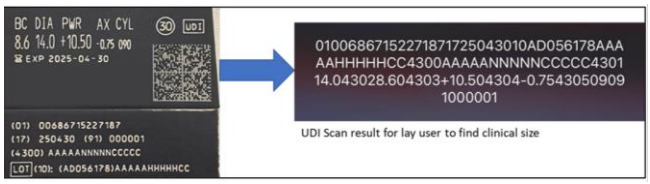
Figure 1 – UDI Levels for Contact Lenses. Master UDI-DI is proposed in red



Initial Master UDI-DI solutions included a grouping of like contact lenses (i.e. Sphere vs Toric) underneath the BUDI (i.e. Material composition) with the Unique Identification remaining on individual lens level. The Master UDI-DI was established to allow registration within EUDAMED without impact to EUDAMED due to high number of Devices. The UDI-DI and Master UDI-DI were to be required on the UDI Carrier, with the Master UDI-DI encoded as a UDI-PI, with only Master UDI-DI registration into EUDAMED. However, the linkage from UDI-DI to Master UDI-DI would be available via the labelling.

Figure 2 – Example of how current clinical size information is available to patients on the carton

Figure 3 – Example of UDI barcode scan result versus Patient prescription



CLRx	Lens Name	B.C.	Dia	Sph	Cyl	Axis
R		8.6	14.0	+10.50	-1.75	90
L		8.6	14.0	+10.00	-1.75	80

Please remove contacts lens if your eyes are red, irritated, painful or light sensitive. The doctor recommends removal of contact lens at night or while swimming.

Solution: ☐ Clear Care ☐ Other _____

Replacement Schedule: ☐ 1 day ☐ 2-4 wks ☐ 2-3 mos ☐ 1 yr

Dr. _____ Prescription Expires in ONE YEAR

Figure 4 – UDI barcode scan result readability Vs clinical size information currently available

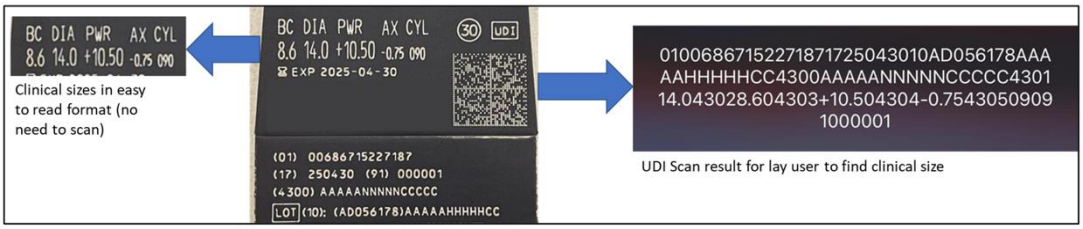


Figure 5 – Contact lens blister trial

Figure 6 – Indication of manufacturing capacity degradation *

	Master UDI	Current UDI Requirements
Print Format		
Print time	847ms	440ms
Cartons Per Minute	35	50

	Master UDI	Current EU UDI Requirements	Additional time for Master UDI	Performance Degradation
Print Time	847	440	407	93%
Cartons per minute	50	35	15	43%

** This is a sample, depending on final solution, actual degradation may be more significant*

Figure 7 - EXAMPLE MADE-TO-ORDER LENSES

MADE-TO-ORDER LENSES (Packs)

UDI Type	Description	Codification	Criteria	Example
BUDI Basic UDI	Unique Device Identification	GMN Global Model Number 25 characters	By Family (same raw lens material)	**8433108TF02-SiliconeLMN** All contact lenses manufactured with silicone hydrogel
UDI- DI	Device Identifier	GTIN Global Trade Item Number 14 characters	By each Brand, Lens Material, Geometry & Packaging quantity	Within a brand, i.e. Saphir Rx, a Unique GTIN is assigned to each combination of Silicone hydrogel lens material and geometry as for example Multifocal Toric, as well as per each packaging quantity Saphir Rx MF Toric 1pk 08445773220088 Saphir Rx MF Toric 3pk 08433108053869 Saphir Rx MF Toric 6pk 08433108053951
UDI-PI	Production Identifier	AI Application Identifier (10) lot (17) expire date	Traceability Lot & Expire date	Printed on cartons for a Saphir Rx MFT 6pk: Unique Lot number for each pack, associated to the clinical parameters. Expire date. 

MADE-TO-ORDER LENSES (Blisters)

UDI Type	Description	Codification	Criteria	Example
BUDI Basic UDI	Unique Device Identification	GMN Global Model Number 25 characters	By Family (same raw lens material)	**8433108TF02-SiliconeLMN** All contact lenses manufactured with silicone hydrogel
UDI- DI	Device Identifier	GTIN Global Trade Item Number 14 characters	By each Brand, Lens Material, Geometry & Packaging quantity	Within a brand, i.e. Saphir Rx, a Unique GTIN is assigned to each combination of Silicone hydrogel lens material and geometry as for example Toric, as well as per each packaging quantity Saphir Rx Toric 1pk 08445773220095 Saphir Rx Toric 3pk 08433108684018 Saphir Rx Toric 6pk 08433108053920
UDI-PI	Production Identifier	AI Application Identifier (10) lot (11) manufacturing date (17) expire date	Traceability Lot, Manufacturing date & Expire date	Printed on blisters: -Unique Lot number for each individual contact lens manufactured. -Parameters are linked to the lot number 

Millions combination of parameters

The M-T-O lenses have million of combination of clinical parameters by each model

Example Saphir Rx

PARAMETERS	
Base curves (mm)	6.80 to 9.80 (0.30)
Diameters (mm)	13.00 to 16.00 (0.50)
Spheres (D)	±30.00 (0.25)
Cylinders	-0.75 to -8.00 (0.25)
Axes (°)	All (1°)
Additions	0.50 to 4.00 (0.50) CD/CN

mark'ennovy currently assigns an unique lot number for each lens manufactured.
The lot is associated to a specific combination of parameters.
Therefore, there is a correlation in the data system between the lot number and the parameters associated to each unit.
The traceability of the product is warranted.

Clinical parameters are already available on human readable on labelling

Cartons

Blisters