Unique Device Identification (UDI)
Frequently Asked Questions

Why are these changes taking place?
Due to the FDA regulation published on September 23, 2013, CooperVision is engaged in a program to update package labeling in order to comply with the new medical device labeling standards.

What product packaging will be updated?
Due to anticipated global UDI legislation, CooperVision has taken a global approach to label redesign. All labels will eventually be updated.

September 2014: The following product labels will change, including private brands and over-label brands that are made from these base products:

- Biofinity Toric
- Biofinity XR
- Biofinity Sphere
- Biofinity Multifocal
- Biomedics Toric
- Biomedics 55 Premier

Is everything about the label changing?
No. There are certain regulatory requirements that must be maintained. For example, the UPC number and barcode will remain on every product carton. The lot number, expiration date, and "Made In" information will also remain on the carton labels.

What is changing?

1. The lot number and expiration date will be contained in a different type of barcode known as a "2D Data Matrix". Customers who have lot controlled inventory will need to be able to scan the 2D data matrix.

2. Single trial blisters can no longer be distributed in the US without some form of secondary packaging. CooperVision will *put Extended Wear Class III single trials* into "Convenience Kits" prior to shipping. In most cases, convenience kits will ship separately resulting in two shipments to fulfill one order.

3. The date format of expiration will change from YYYY/MM to YYYY-MM-DD.
    - The day of the month will default to the last day of the month.
    - Since the requirement for the new date format applies to all medical devices, CooperVision will change all blister, vial, and finished good cartons to the new expiration date format.
    - During the transition period there will be situations where the blister is labeled with a YYYY/MM date and the carton bears a YYYY-MM-DD date. The opposite may also occur: Blister = YYYY-MM-DD and Carton = YYYY/MM.

- Additionally, there will be some scenarios where the blister is marked with, for example, 2019/04 and the carton marked with 2019-03-31. The short dating of the carton is intentional.

When are these changes taking place?

Between August 24, 2014 and September 12, 2014:

- Class III (Extended Wear) device labeling will be changed

Beginning 2015:

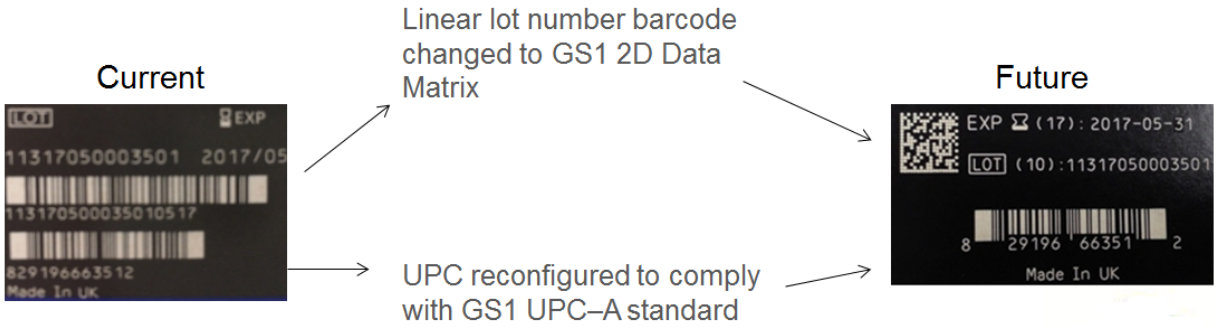
- Class II (Daily Wear) device labeling will begin
- September 24, **2016** – FDA requirement due date

Who does this affect?

- Most customers will have minimal impact, if any, due to the labeling changes associated with the UDI regulation
- Only those that use lot codes for inventory will need to be aware of the change
- We can supply you with sample barcodes to scan to make sure you can process the GS1 barcode. For more information on GS1 barcode visit www.gs1.org

Examples of the labeling change:

Biofinity Cartons (Label on the back panel)



Biomedics Cartons (Labels on carton end panels)