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Case Study: Medreich | Anti-Tampering and EU FMD



See how CMO Medreich PLC developed a compliant label for its EU FMD-compliant anti-tampering devices for prescription medicine packs, all while protecting the efficiency of their line systems. Medreich’s poster, “Medreich PLC Designing and Using of Anti-Tampering Device,” was one of 11 featured during FutureLink Barcelona’s interactive Poster Sessions.



Business Challenge

- As part of the Falsified Medicines Directive (FMD) which came into force on 09/02/2019 it was required that all Prescription Medicines have Anti-tampering device on them
- Upon opening the pack, the regulation states that the rest of the FMD printed information should still be readable
- The Anti-tampering device should continue to seal the packs until at least the use by date of the medicine

Outcomes

- To cope with the issue of not damaging the printed FMD information we decided to go with a perforated sticker
- To make it easy to see if a sticker is applied we decided to add a black line down the middle
- We also did studies of how effective the glue was by applying the Anti-tampering device to box's and placing in stability cabinets
- Once we had started testing we discovered an issue with the cutter lines, these were causing glue to leach out of cut design
- At this point we started the second design with no cutter lines and this has proved much more efficient, with less impact on machine downtime



1st Design

Black line denotes cutter guide. (This is not printed)

Title: Tamper proof seals option1_Medreich plc
Label Size: 25mm x 20mm with internal cuts & printed line.
Colours: Black
Rads: 1.5mm
Black line denotes cutter guide. (This is not printed)

Rewind info:
1 Across
Wide edge leading on rolls
register mark runs down the label

2nd Design

Title: Tamper proof seals option1_Medreich plc
Label Size: 25mm x 20mm with internal cuts & printed line.
Colours: Black
Rads: 1.5mm
Black line denotes cutter guide. (This is not printed)

Rewind info:
1 Across
Wide edge leading on rolls
register mark runs down the label

Recommendations

- Run line trials on different ATD design variations, to arrive at the best possible material which will run affectively in the production process
- Place sample ATD cartons on stability trials to see if ATD performs well in all the variable conditions
- Choose the correct size ATD, to give the best possible contact area on the carton
- Work closely with ATD manufacture to ensure the correct adhesive is used when the ATD are produced
- Review carton designs and make changes to braille positions on cartons, so that ATD in not covering the braille area
- When looking at the application of the ATD on production lines, think about how the reject system will work on cartons with ATD missing
- Check on ATD placement during production run, as 2D print must not be covered by ATD



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Case Study

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