

Statement to Falsified Medicine Directive (Directive 2011/62/EU)

The European Union started to strengthen the security of patients within its member states by introducing the Falsified Medicine Directive (Directive 2011/62/EU) which applies since January 2nd 2013 to all EU member states. The Directive provisions shall be fully implemented until February 9th 2019.

The Falsified Medicine Directive defines new rules which strengthen the security of medications throughout all parts of the supply chain towards the patient.

The authenticity of any medicine will be defined by two additional features on the box:

- The Unique identifier (UI) a D2 matrix code that is individual for each box
- The Anti-Tampering –Device (ATD) which enables to check if the medicine packaging is in the original state

Through those two safety features an authentication of the box will be done before the packaging is dispensed to any patient already at the level of the pharmacy.

Technology used to authenticate the secondary packaging:

- The UI is applied in-line at the pharmaceutical packaging line
- The individual D2 matrix codes applied by one of the methods:
 - inkjet technology
 - laser ablation technology

We hereby declare that, since 2011 International Paper supports research and development of testing methods related to both ink-jet and laser codeability, by supplying material for tests and verify performance of our products.

International Paper made it a standard, to test both GC type folding box boards: Alaska Plus and Arktika on a regular basis at Papiertechnische Stiftung (PTS).

Both board grades continuously achieve good results, which is confirmed by regularly updated FFPI/PTS certificates.



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