

AlpVision SA
Rue du Clos 12
1800 Vevey
Switzerland
Tel : +41 21 948 6464 avinfo@alpvision.com
Fax: +41 21 948 6465 <http://www.alpvision.com>

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For more information contact: Roland Meylan, Corporate Communications Manager
roland.meylan@alpvision.com Phone: +41 21 948 6464

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AlpVision Krypsos™ open platform to combat counterfeits has successfully achieved compliance with the software and quality requirements of the pharmaceutical industry and health authorities

Krypsos is a server-based online authentication system managing the Cryptoglyph packaging covert security solution, which only requires standard ink and standard printing processes (offset, rotogravure, laser, inkjet, etc.), as well as other security features such as Fingerprint™, the AlpVision detection solution based on intrinsic characteristics of the product. Third party overt features such as Bar Codes, two dimensional matrix codes or OCR can also be managed.

For major deployments, which will bring covert protection to over a billion products worldwide by first quarter 2008, AlpVision Krypsos successfully achieved compliance with the FDA 21 CFR Part 11 requirements for Electronic Records and Electronic Signatures (ERES) issued by the Department of Health and Human Services of the US Food and Drug Administration (FDA).

The Krypsos online authentication solution enables branded product manufacturers to provide their supply chain with a single point of contact for both fraud detection and genuine product authentication. It also provides valuable logistics data, such as gray market consolidation, and can generate helpful online notifications for mobile commerce.

Krypsos meets FDA 21 CFR Part 11 requirements providing the following functionalities:

- Audit trail documentation;
- Electronic records;
- Advanced security controls and password protection;
- Event reporting and notification including: times, actions, users, and more;
- Central data storage in a single SQL database.

The Computer Systems Validation (CSV) was performed in compliance with the V-Model, which defines the relevant project documentation under the responsibility of either the customer or AlpVision.

AlpVision has also a full Quality Assurance (QA) system in place, which notably includes: development standards, document management, operational handbook, network and security management, risk analysis and contingency planning.

The management and development teams of AlpVision are proud to announce this important step, showing its ability to master complex software development in compliance with extremely severe QA policy established in the environment of large multinational firms.

AlpVision is also proud to see its anti-counterfeiting solutions adopted by major players in the fast moving consumer goods (FMCG) and pharmaceutical industries, in order to protect their products worldwide. The AlpVision solutions include a covert security feature to ensure the security of an overt product identifier. The covert security feature is applied using only standard ink and standard printing processes (offset rotogravure, laser, inkjet, etc.). This technique is perfectly in line with the anti-counterfeiting requirements of the FDA Revitalization Act S.1082 for medicines delivered in the USA.