



Alysidia



Smart tools for compliance e-IFU/eManuals Solution

WE PROVIDE AN INNOVATIVE TOOL TO MANAGE YOUR IFU DIGITALLY AND IN FULL COMPLIANCE WITH MDR REGULATION.
THIS WILL RESULT IN HUGE SAVINGS AND BURDEN REDUCTION FOR YOUR COMPANY.

KEY FEATURES:

- Web App
- Dedicated back end to manage documentation
- Revision management
- Guarantee that only approved templates and content are used with version control
- QR scan and download
- Personalized front end
- Language management
- Product family grouping
- Multidocuments management
- Local language self recognition
- Blockchain Audit Trail

Our tools are fully compliant and ready to use.

Reach out to ask for a Demo.

Key Benefits

Save on printing and managing all related paper process

Developed by Regulatory Compliance Experts

Organize all your instructions for use and make them available to your customers

DON'T BREAK THE SEAL - review product documentation without having to break your products seal.

Tamper Proof via blockchain

Audit trail compliant to 21 CFR Part 11 on Blockchain

Quick and easy retrieve via QR code Scan

From an off-the-shelf solution to a fully tailor-made platform.

SAVE PAPER AND COSTS

What does your company spend on packaging, paper, printing, logistics and the management of all that?



STAY Compliant

solution fully compliant with EU and FDA regulations ([MEDDEV 2.14/3 for IVD](#) and [Commission Regulation \(EU\) No. 207/2012 on MD](#))

Requirement on the risk analysis and risk evaluation about eIFU:

Content shall cover at least the requirement of regulation 207/2012, art. 4

The aspects mentioned in art. 4 of regulation 207/2012 should be covered thoroughly in the risk management file. The information can either be included in a separate risk evaluation or included in the existing risk management file.

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CONTACT US FOR OFFER OR SPECIFIC SUPPORT

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Alysidia.com



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Smart tools for compliance e-Certificate

THE ISSUE: COUNTERFEIT CERTIFICATES THREAT

Counterfeit certificates is a common issue in daily business, especially in time of urgent need.

Certificates are usually issued by notified bodies or third party legal entities which are authorized by the European community in the EU or specific governing authorities to perform conformity check to specific rules or standards in order to make sure a certain product is safe for its intended use.

The market has seen a big wave of fake certificates being issued during the peak of the pandemic in April and May 2020.

Several alerts were made by European Community and ESF <https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe>

Many manufacturers from China and the East used fake certificates in order to enter the PPE and medical device market quickly and without following the proper

REGULATORY PATH.

Setting a **big threat on public health** and creating big confusion, making the delivery also of properly developed medical devices more complex and delayed.

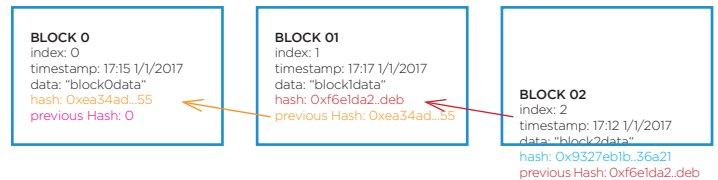
Currently, there is no concrete solution to prevent certificate counterfeit and cyber manipulation of already issued certificates by criminals.



OUR SOLUTION

We have therefore developed an effective and easy-to-use certificate management tool.

The tool allows storing certificates of any kind into a safe database backed by **blockchain** allowing to make the certificate **tamper-proof and immutable**.



Using blockchain makes altering the certificate impossible for hackers or criminals.

ALYSIDIA E-CERTIFICATE PLATFORM FEATURES:

We have therefore developed an effective and easy-to-use certificate management tool.

- User-friendly cloud based Azure web app
- Cool Dashboard to review the certificate status and statistics
- Revision management with Audit Trail on Blockchain
- Certificate approval management with Blockchain Audit Trail
- Certificate storage on the blockchain
- The platform allows only authorized users to load up or change the verified certificates.
- Easy and free access for the general user to the stored certificate by simple search bar query or QR scan
- Download feature

Our solution is already in used by medical device companies and notified bodies.

REACH OUT TO US OR BOOK A DEMO TO KNOW MORE

POSSIBLE APPLICATION:

- Quality Certificates
- Training certificates
- Lab Testing
- Authenticity
- Proof of Origin

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