



The potential of the e-Signatures in medtech sector: Fact check 2024



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Dear Readers,

We are delighted that this guide has found its way to you. Behind every action is a motivation. Your motivation to engage with digital signatures can be diverse. You may want to become more "digital" in your company, have a mandate regarding the protection of your business data, or are basically looking for ways to make important business processes more efficient.

Our motivation is to provide our users with an all-in-one platform for legally valid, data-secure and efficient signature processes in the European business area.

This guide has been written with the aim of providing all readers with the essentials of digital signature workflows in the corporate context without any frills. We welcome any business person who is interested in digitalisation "Made in Europe for Europe". We hope that this guide will provide you with valuable information, food for thought or help you get started with the introduction of a signature platform.



Dr. Clemens Brunner | CEO & Co Founder of sproof

Dr. Fabian Knirsch | CEO & Co Founder of sproof

Sign yourself >

Invite contacts >

Save template >

Edit form >

Progress >

Dr. Thomas Hetta
 Signed >

Dr. Lisa Maier
 Signed >

Introduction

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Why sign digitally now?

There is hardly a company, regardless of size and industry, that has not benefited or would not benefit from the introduction of digital signatures. The digital alternative to handwritten signatures is regulated and recognized by law in Europe and is considered equivalent to paper signatures when used appropriately.

Digital signatures are now also used by large companies with strict IT policies or in the public sector. The advantages for companies in various sectors, but also for private individuals, are manifold.

Accelerate your approval processes, save measurable resources.

medical technology

Challenges

02

The digitalization of the medical technology industry is essential to increasing efficiency and meeting the demands of modern healthcare. It enables seamless traceability of medical products, facilitates compliance with strict regulatory requirements and speeds up the approval process for new technologies. In today's world, the credo is: *if you don't sign digitally, you lose*

The traditional method of printing and scanning medical documents is error-prone and insecure as it leaves room for human error and data manipulation. Digitization offers a faster and secure alternative that improves data exchange and increases the quality of patient care. It also lowers operating costs by reducing paper costs and physical storage space. The medtech industry must drive digital transformation to remain competitive, optimize patient care and meet regulatory requirements.



Solution

Digital signatures in medical technology 03

- ✓ Reduction of personnel costs through efficient signature processes
- ✓ Reduction in costs and logistics for paper-based processes
- ✓ Acceleration of processes through faster approvals
- ✓ Maximum security, legal validity and compliance for all contractual processes, including GDPR, FDA and eIDAS compliance
- ✓ Mapping of all signature processes within the company and with external stakeholders

Medical technology is subject to very strict regulations and standards (MDR, FDA, etc.) for a good reason: the highest quality standards are a prerequisite for the health and safety of patients.

All processes relating to the design, manufacture and delivery of finished medical devices must be fully documented by law. This results in an unmanageable amount of bureaucracy. Almost all processes involved require approvals: The signature is an essential sub-step or often the critical bottleneck in many processes.

Speed up your company with the digital signature!



1. Increasing process speed
2. Ensuring security & compliance through highest evidential value
3. Improving usability within the company as well as in collaboration with external parties.

Use cases of an all-in-one e-Signature platform

04

An electronic signature platform should be able to cover all possible signature processes that can occur in a corporate context. The most important use cases are described here. sproof sign has specialized in the comprehensive representation of all common use cases.

Sign digitally yourself

The documents are located on your "digital desk" or in your digital dashboard, which gives you an overview of all your documents. You can now decide for yourself which signature standard (advanced or qualified) you want to use to sign one or more documents. No scanning, no trip to the printer, no paper.

Obtain digital signatures externally

Obtain important signatures from multiple parties according to the desired standard and monitor the progress of your signature processes at any time. The parties receive a signature invitation via e-mail and can easily sign with legal validity.

In addition, one platform helps you to design all signature processes and workflows intelligently. sproof sign is unique in the handling of qualified electronic signature processes and has integrated all governmental and non-governmental providers (e.g. D-Trust, ID-Austria, mobile signature, etc.).

Define and save defined signature workflows

A signature workflow is a set of terms and conditions that you will find in your typical signature processes:

- Desired signature standard
- Desired signature position
- Completion date
- Form fields

Sign digitally in a team

You work in a team or lead a team. The digital signature creates security and conformity for all signature processes that you want to handle internally. There is an admin for each team to control the signature quota, members and special settings.

Integrations & API

You can use sproof sign 1) as an add-on in your usual Office tools. You can find an overview of the tools in which sproof sign is integrated [here](#). 2) You can also handle your signature processes via the well-documented API interface. Moreover, you can implement sproof sign directly (e.g., as an iFrame) into your own web solution. [Learn more.](#)



Highly secure cloud, ready to use immediately

sproof sign is a web-based solution for digitally signing contracts and works on all mobile devices (desktop, smartphone, tablet). sproof sign is based in Austria and all data is backed up exclusively in data centers within the EU. We guarantee GDPR compliance at all levels, both with us and with our subcontractors. We offer these guarantees to our customers in a data processing agreement (DPA), which is based on the EU standard contractual clauses, thus also offering the highest level of legal security.

Interfaces & existing systems

- sproof sign can be seamlessly integrated into your existing systems.
- Sign directly in common tools such as MS Teams, Word, Google Drive etc. ([list of all integrations](#)).
- Single Sign On
- Simple API for customized use cases. ([API documentation](#))

Document Storage & Progress Monitoring

Important contracts are stored in a central location in a clear, highly secure and encrypted manner. Nevertheless, documents can be accessed at any time and from any location. In addition, the progress of the signature processes can be viewed at any time and reminders can be sent if required.

Qualified (QES) and advanced (FES) electronic signing including identification.

sproof sign supports all types of electronic signatures (simple, advanced, and qualified) according to the eIDAS regulation, as well as many other globally widespread signature standards (e.g., FDA Compliance).

Batch Signing: Sign Contracts Simultaneously

With the batch signature, countless documents can be digitally & legally signed in a single operation. An enormous time saving.

Document Portfolio: Send Out Contracts Simultaneously

Digitally compile multiple documents and send them out together for signing. This saves a lot of time for both you and the recipients.

Corporate Branding, Company Stamp & Signature Styles

Whether you are a large team or a single user. In sproof sign, you can store your own company logo as a company stamp. You can also create various signature styles for different purposes.



eID Hub: Obtain Signatures Across Europe

The qualified signature is legally equivalent to a handwritten signature throughout Europe. sproof sign, with its unique interface, allows the signing of contracts with various qualified signature providers. This is a significant advantage in the procurement and issuance of legally valid signatures. Click here for an overview of all integrated [trust service providers](#)

Verify Signatures & Download Audit Reports

You can check the validity of the applied electronic signatures directly in sproof sign with a click of the mouse. You can also download a verification report for each signature run and see who signed with which certificate and when.

Team Management & Delegation Rules

sproof sign enables straightforward user and rights management for individuals within a plan. Additionally, signature quotas can be centrally managed, and various crucial settings can be configured for the entire plan.

Support & Academy

sproof sign is known for its fast and flexible support. The sproof sign Academy is a free training portal that helps you and your employees get off to a quick start.

Transparent pricing with no hidden costs:

Our goal is to be the unrivaled best choice when searching for a suitable signature provider. We prioritize fairness and transparency, two values that shape our corporate culture. These values also guide the pricing of our solution in the enterprise segment.

"IMPORTANT CHANGES BEGIN WITH
A SIGNATURE."



Case Study

W&H Dentalwerk Bürmoos GmbH

06

Specific use cases for digital signatures at W&H

Digital signatures play a particularly important role in internal signature processes for product development processes at W&H. This includes the digital signing of test protocols, plans and designs as well as projects that influence the development process and are FDA-relevant.

sproof sign ensures comprehensive traceability through the audit trail, which documents exactly who signed which documents and when. The information is integrated into the operating system and the workflow includes logging in, signing with sproof sign and automatic filing in the product management system. This creates a continuous audit trail as a 'single point of proof' for product documentation.

In terms of the production process, the digital signature has a significant impact on efficiency at W&H. In a highly dynamic environment in which products are produced within 24 hours of receipt of an order, the conventional manual process of printing, signing, scanning and archiving paper documents is impractical. The digital signature is therefore an essential part of the entire production chain, enabling acceleration without sacrificing efficiency.

1890

Founded

28

Locations

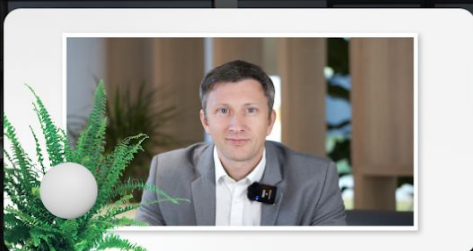
130

Countries

1.300

Employees

[Case Study →](#)



W&H is one of the world's leading manufacturers and developer of medical technology products. Specializing in the dental industry. With the introduction of sproof sign, the internal product development cycle has been greatly accelerated and streamlined.

Security concept

Data Privacy, Legal Validity, & Compliance

07

Data Privacy

Data privacy is not an add-on for us; it's our mission. We guarantee GDPR compliance on all levels, both internally and with our subcontractors. These assurances are provided to our customers through a Data Processing Agreement (DPA) based on the EU's Standard Contractual Clauses, ensuring a high level of legal certainty.

sproof is headquartered in Austria, and we exclusively store data in EU data centers, eliminating any connection to third countries during data storage, especially not in the USA. Furthermore, sproof is an IÖB-awarded solution, recognized for its suitability for deployment in public administration.

IT Security Aspects

sproof offers the highest level of IT security. We operate our applications redundantly and fail-safe at several locations in the EU. Your data is stored securely and all connections are encrypted and authenticated. Our applications are subject to constant monitoring and regular internal and external audits and checks.



eIDAS Compliance

sproof sign fully complies with national and international guidelines. Europe has the most stringent international signature law. The basis is the eIDAS regulation (Electronic Identification, Authentication, and Trust Services). This serves as a valid framework in all EU/EEA member states. All processes designed with sproof sign adhere to these high standards. Therefore, signing with sproof sign is 100% legally valid.

FDA Compliance

sproof sign complies with FDA 21 CFR Part 11, making it suitable for all industries subject to this legal framework.

ISO 27001 Certified Servers

Our data centers are, of course, ISO 27001 certified, meeting the highest standards of IT, data, and quality assurance requirements.



The market for digitizing signature processes is growing, and the demand is high. We have analyzed our competitors and are staying abreast of developments to provide our customers with the best offerings.

The following questions will help you choose the right solution for your use case:

Do you and or your company operate in Europe?

sproof sign is a 100% European software solution and is functionally and feature-wise comparable to well-known e-Signature solutions from the USA.

Caution is advised: US tools can never guarantee the security of sensitive data. The surveillance laws in the USA contradict the fundamental rights of the EU. sproof sign is headquartered in Austria and specializes in the highest level of data protection.

Even if some US solutions are opening branches with offices in Europe, the guarantee of seamless data protection remains questionable. It is time for European companies to also rely on strong European partners for software projects.

Here, we demonstrate how sproof can assert itself through the optimal blend of highest security & compliance and unbeatable functionality.

- [sproof versus DocuSign →](#)
- [sproof versus AdobeSign →](#)
- [sproof versus skribble →](#)

Do you have high demands for legal validity & compliance?

The sproof GmbH is headquartered in Austria, and all your data is exclusively stored in data centers within the EU. There is no data storage in third countries, especially not in the USA. Our data centers are, of course, ISO 27001 certified and meet the highest requirements for IT, data, and quality assurance. sproof sign is also an IÖB-certified solution suitable for deployment in public administration. We guarantee GDPR compliance on all levels, both internally and with our subcontractors. These assurances are provided to you in the form of a Data Processing Agreement (DPA) based on the EU's Standard Contractual Clauses, ensuring a high level of legal certainty.



Do you want to transform your signature processes comprehensively

The broad functionality of sproof sign enables you to map even complex signature and approval processes holistically. We have specialized in the use cases of medium-sized and large companies in which several signature parties, parallel or sequential approval processes or different signature standards are involved throughout Europe.

With sproof sign, you can prepare any contracts and forms in the shortest possible time, sign them yourself, approve them for signature, check their progress and securely store signed documents.

The wide range of functions, coupled with a very high level of user-friendliness, gives sproof sign a unique market position.

Is a fast integration important to you?

The IT managers of our customers are consistently surprised at how easy and, above all, quickly our solution can be integrated into their in-house IT system landscape. Thanks to the cloud!

Our cloud solution is deployed throughout the entire organization within a very short time. There are no maintenance and servicing costs for you. You always use the latest version and operate without the need for your own hardware. The software runs around the clock in our highly available and highly secure data center.

Our experts in IT security and data protection guarantee you the highest security without compromises. Necessary adjustments and changes are implemented promptly and precisely.

Do you prioritize training options and fast, friendly support?

True to our company motto - 'If you confuse, you lose' - it is very important to us to provide the best possible support for our customers and users in using and starting with our tool.

One of the ways we do this is through the freely available sproof sign academy. We make great efforts to explain our application as efficiently as possible and to inform about product updates.

Verify Signatures & Download Audit Reports

You can check the validity of the applied electronic signatures directly in sproof sign with a click of the mouse. You can also download a test report for each signature run and see who signed with which certificate and when.



Are you committed to innovation & progress?

We are a team of IT security and legal tech experts. The basic idea was born in the course of research work in the field of privacy and security science at the Center for Secure Energy Informatics at the Salzburg University of Applied Sciences.

The founding team around Dr. Clemens Brunner, Dr. Fabian Knirsch and Erich Hoepoldseder started with the vision of providing the first comprehensive platform for legally valid, data-secure and efficient signature processes in the European Economic Area.

Since then, they have been continuously tinkering, innovating and developing to meet the challenges and dynamics of European business transactions with a constantly evolving all-in-one solution for digital signatures.

Standing still is a step backwards. We follow our mission to constantly adapt our platform for the benefit of our users. With success. Many industry leaders from different sectors already rely on sproof. Trust in security - Made in Europe.

Do you want transparent cost structures without hidden fees?

We communicate our cost structure very transparently and can communicate a fixed and comprehensible price. Without any additional fees, service charges or other "on-top costs".

We have a reputation that we are proud of: We take time for our customers. We carefully analyze the signature processes of potential interested parties. We know how to assess the potential of our platform depending on the use case, corporate culture or industry and are honest if our solution does not fit your problem.

Number 1 in the e-Signature Category

OMR Reviews is a reputable, independent review platform for European B2B software. As of Q1 2024, sproof sign is currently the highest-rated and most reviewed provider in the 'e-Signature' category.



Process

Introduction & Integration

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Getting started with sproof sign only takes a few minutes for small teams and only a few hours even with deep integration into the entire IT landscape of a large company.

The reason: you don't need any hardware, sproof sign is a cloud solution that is operated around the clock in a highly available and highly secure data center.

The users designated in your company are added to your company plan in sproof sign by email and optionally provided with a qualified electronic signature.

Users are automatically sent helpful documents and links to make getting started with sproof sign as efficient and easy as possible.

The admin of the company plan has the option of making various settings for all users in order to control the signature processes according to the use cases.

"Thanks to the cloud, the onboarding process only took a few hours and was consistently supported by sproof."



Learn more

Additional Resources

We are committed to providing all our users with essential information and updates about the sproof sign platform. To achieve this, we have established various channels.



sproof sign Academy:

[Helpful Guides and Videos →](#)



E-Book:

[The Integration of e-Signatures →](#)



Webinars:

[We regularly invite you to informative online events →](#)



Newsletter:

[Don't miss any updates →](#)



Blog:

[Know-How and FAQs about e-Signatures in our Blog →](#)





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to sign documents in Europe

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Find the link to the full white paper in the comment section ↴

