



# CERTIFICATE

ProCert, accredited certification body, certifies that the company mentioned below fulfils the requirements of the standard mentioned below:

## Silicon Brain SA

Place de la Libération 10  
4430 Ans (Belgium)



Standard

**Quality management system (ISO 9001:2015)**

Scope of application

**Silicon Brain, 4430 Ans (Belgium)  
Silicon Spirit, 9991 Weiswampach (Luxembourg)**

Field of activity



**Development and edition of ERP software**



Initial certification date: 06 March 2019

Issuing and certification date: 06 March 2019

This certificate is valid up to and including: 05 March 2022\*

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\* Subject to suspension or withdrawal of certification at any time. Only ProCert's public register (accessible under www.procert.ch) attests validity of this certificate.



# ISO 9001 :2015 Certification



As of the 6th of March 2019, Silicon Brain and its innovation center Silicon Spirit are ISO 9001:2015 certified

## What is ISO 9001:2015 ?

ISO 9001 is a standard, specifying requirements for a **quality management system**. It helps companies and organizations improve efficiency and enhance customer satisfaction.

The latest draft was published in 2015, hence the name ISO 9001:2015.

Every year, Silicon Brain and Silicon Spirit activities will be audited by a certification body who will control that the ISO 9001:2015 requirements are being met.

## What is a quality management system ?

A quality management system is **the whole set of activities** implemented by an organization so as **to determine the demands of its customers** and other interested parties to its activities.

The 7 quality management principles are :

- Customer focus
- Leadership
- Staff participation
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management with interested parties

## In practical terms, what does it mean for the end customer, the installer ?

It mainly means that Silicon Master Suite software are being **analyzed, developed, produced, tested and released** respecting a set of thought out **processes**, using adapted **tools**, adding to all this the constant pursuit of **continuous improvement**.

In practicality, for the end customer and the installer, it means that the quality of Silicon Brain provided products and services undergoes continuous improvement and that customer satisfaction is the central focus of our concerns.

## Are the Silicon Master Suite software ISO 9001, ISO 13485 or FDA 21 CFR Part 11 certified?

**No**, a piece of **software** used to manage/manufacture products **cannot be certified** under these standards, which set the standardization of the overall functioning of a body.

However, the software publisher Silicon Brain and its innovation center Silicon Spirit are ISO 9001:2015 certified and that partly meets the requirements for stability and management of change that interest us.

## Can the Silicon Master Suite software help my organization get ISO 9001, ISO 13485 or FDA 21 CFR Part 11 certified ?

**Yes**, the many **functionalities** of the Silicon Master Suite software make it possible to fulfill many of the provisions set out in those standards.

Among others, our applications offer the following standardized features :

- Materials traceability (management by batch)
- Operations traceability (routing circulation)
- Locking flows
- Authorization signature before release
- Releases presentation and management for support material (assembly instructions,...)
- Management of products releases manufactured with an approval flow.
- Logging of modified data (information traceability)
- Staff skills management and working authorizations
- Management of non-conformities, exemptions and requests for improvement
- Quarantining, qualification, downgrading
- Management of metrology and instruments maintenance
- Quality determination using AQL sampling methodology
- Warning and switching to enhanced controls using a SPC control card

This is nonetheless insufficient. The second part of the standards pertaining software in use, revolves around their **stability** and **management of changes**. The ISO 9001:2015 certification of the software publisher Silicon Brain and its innovation center Silicon Spirit help partially meeting the requirements in question. But because of the infinite combinations of configuration and customization, Silicon Brain cannot possibly verify every single case. That is why the organization pursuing certification needs to implement a validation process for critical operations, to be launched before every single update.

## Does Silicon Brain run their own software for its operations ?

Yes, of course. Our software are at the heart of our quality management system, notably for managing action plans. Moreover, we are convinced we should be the first to use our products so as to always work on improving them.