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# Business Case

How the long-term collaboration between Fabrinal and Medidee supports the competitiveness of the Swiss Manufacturer

TÜV SÜD ISO 9001 TÜV SÜD ISO 13485

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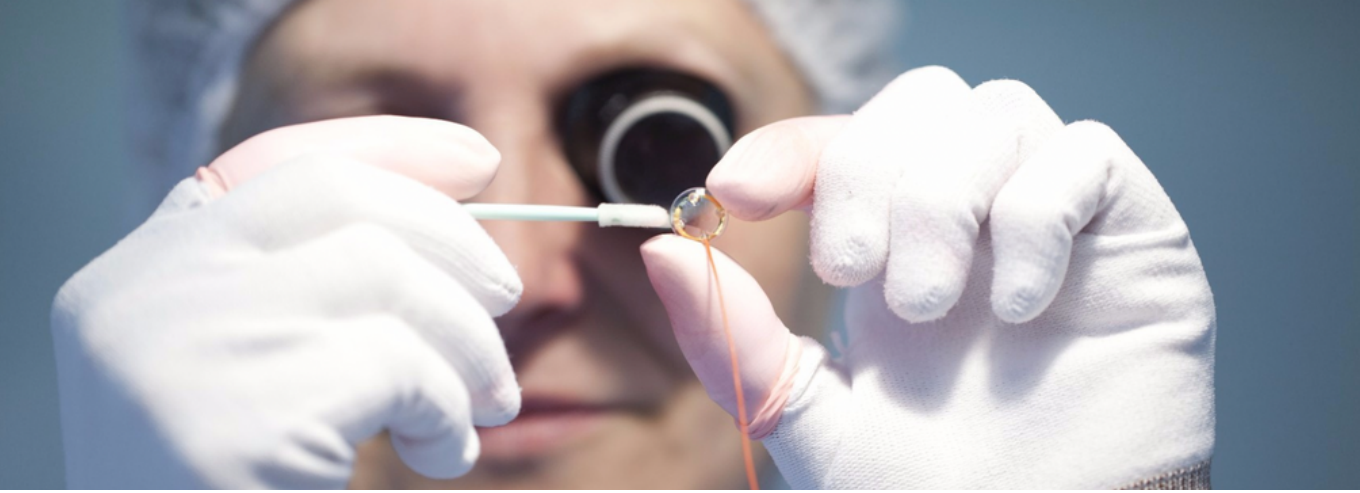
# INTRODUCTION

This Business Case introduces the collaboration between Fabrinal, an SME focused on medical **technologies applied to the eye**, and Medidee, a global **regulatory service provider** for Medical Devices.

Through this Case, we provide a real-life example of how the successful joint work between both companies has contributed to Fabrinal keeping the company's regulatory situation under control, allowing **business activities to develop in an effective, innovative and competitive way**.



# FABRINAL

Fabrinal is a Swiss SME manufacturing medical devices that help to diagnose multiple eye pathologies. Its developments have been launched and are supervised by ophthalmologists of international renown. Some of the company's devices have been on the market for more than 15 years.

Fabrinal's products are **class IIa devices** under regulation (EU) 2017/745. Two devices are designed to support the diagnosis of retinal dysfunctions and another to wash the anterior chamber of the eye.

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# CHALLENGE FACED

With the Medical Device Regulation (MDR 2017/745), Fabrinal's Technical Documentation (TD) and Quality Management System (QMS) needed a full revision, to **ensure alignment with all the new requirements**.

Moreover, several standards applying to the devices (such as **EN ISO 11607-1 and 2:2020**, **ISO 20417 : 2021**, **ISO 15223-1 : 2021**) had been revised in the previous 2 years, leading to the need for new label tests, IFU and label updates, among others.

With the programmed MDD Declaration of Conformity expiration, making a complete revision of the company's documentation was **mandatory to maintain sales.**

# COLLABORATION WITH MEDIDEE

Medidee has been working with Fabrinal for almost 10 years. This long term relationship enabled a smooth MDR transition.

Medidee helped by:

- revising several **Standard Operating Procedures** (SOPs), such as Vigilance and PMS
- updating **Biological Risk Assessments** (BRAs), **Clinical Evaluation Reports** (CERs), as well as **restructuring the TD completely**
- mandating various test labs to **complete or update tests** linked with biological evaluations and transport validation for sterile devices
- writing the associated plans and reports to ensure compliance with all applicable standards and **General Safety & Performance Requirements (GSPR)**.

The close collaboration with Fabrinal's management enabled an optimised balance between tasks directly performed by Fabrinal's team and Medidee's deliverables.

# RESULTS ACHIEVED

As a result of this collaboration, all the elements have been submitted, and Fabrinal is **now safely engaged in conformity assessment process.**

> Fabrinal has been supported closely for almost 10 years by Medidee. For an SME of our size, this change is so critical from a timing and economic point of view, that it is crucial to be advised by rational and experienced experts. I am extremely confident about their advice and application of the MDR and can navigate through this challenging change a bit less worried.
>
> **Cloé Houriet, CEO of Fabrinal**

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Since 2013, Medidee offers consultancy services in **Quality Assurance**, **Regulatory** & **Clinical Affairs** and **Digital Health**, supporting MedTech companies of all sizes, from idea to market.
We are ISO 13485 & ISO 9001 certified.

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