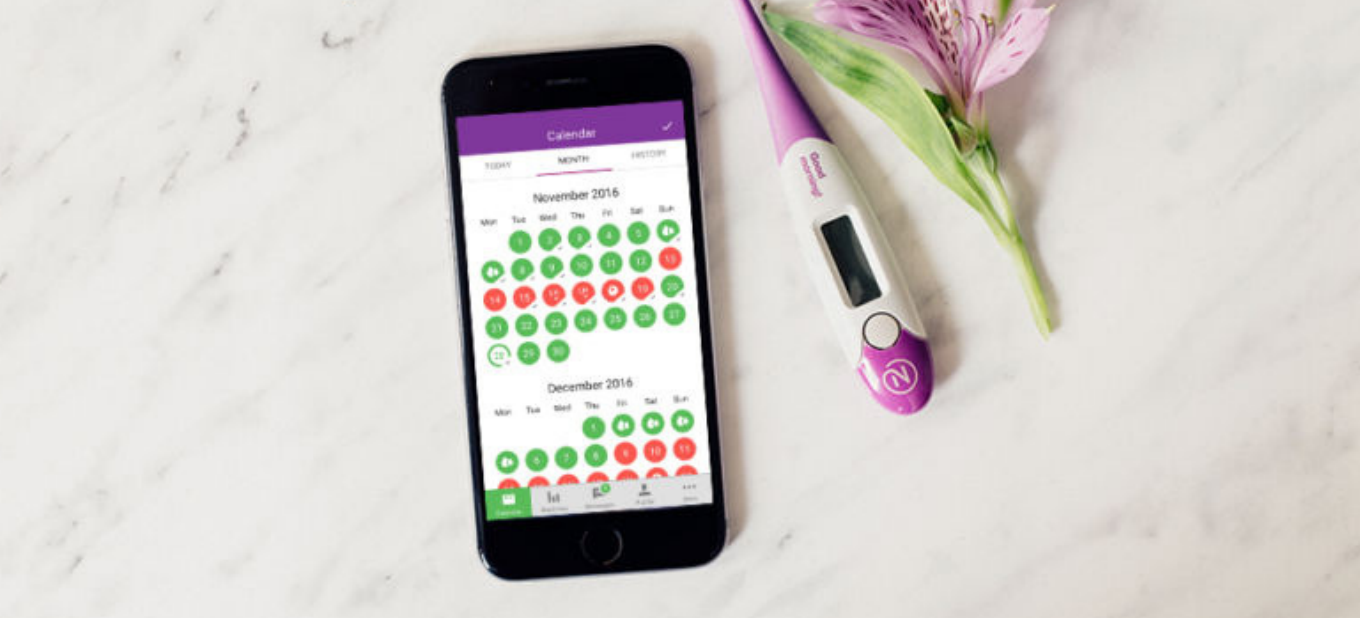

Natural Cycles

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Business Case

Certifying a one-of-a-kind, innovative mobile app under the MDR

TÜV SÜD ISO 9001 TÜV SÜD ISO 13485

Medidee - Now a Part of Veranex

INTRODUCTION

This Business Case introduces the collaboration between Natural Cycles, a company providing a **revolutionary approach to birth control and family planning**, and Medidee, a global **regulatory service provider** for Medical Devices.

Manufacturers of Medical Device Software, such as Natural Cycles, face **increased complexity and tighter timelines** in the current regulatory framework. It is important to know exactly what steps must be taken and how to manage all the requirements effectively.

Through this case, we provide a real-life example of how the successful joint work between both companies has contributed to the **MDR certification of the unique app from Natural Cycles**.

NATURAL CYCLES

Natural Cycles is a Swedish **woman's healthcare company founded in 2013** by former CERN physicist, Dr Elina Berglund and her husband Dr Raoul Scherwitzl.

The company is best known for the Natural Cycles app, a natural method of birth control that uses an **Artificial Intelligence algorithm**, sensitive to subtle patterns in a woman's cycle, to determine daily fertility based on basal body temperature and period data.

CHALLENGE FACED

As the first of its kind, Natural Cycles had to confront a **stiff regulatory framework** in order to be granted EU and US market authorization for their software application as a non-invasive, non-hormonal contraception method.

Under the Medical Device Regulation MDR 2017/745, the Natural Cycles app is a **Class IIb medical device software** as per Rule 15 of Annex VIII.

Early on, the company contacted Medidee requesting support to achieve CE marking, at that time under MDD. This marked the beginning of a **collaboration that now counts more than 7 years**.

COLLABORATION WITH MEDIDEE

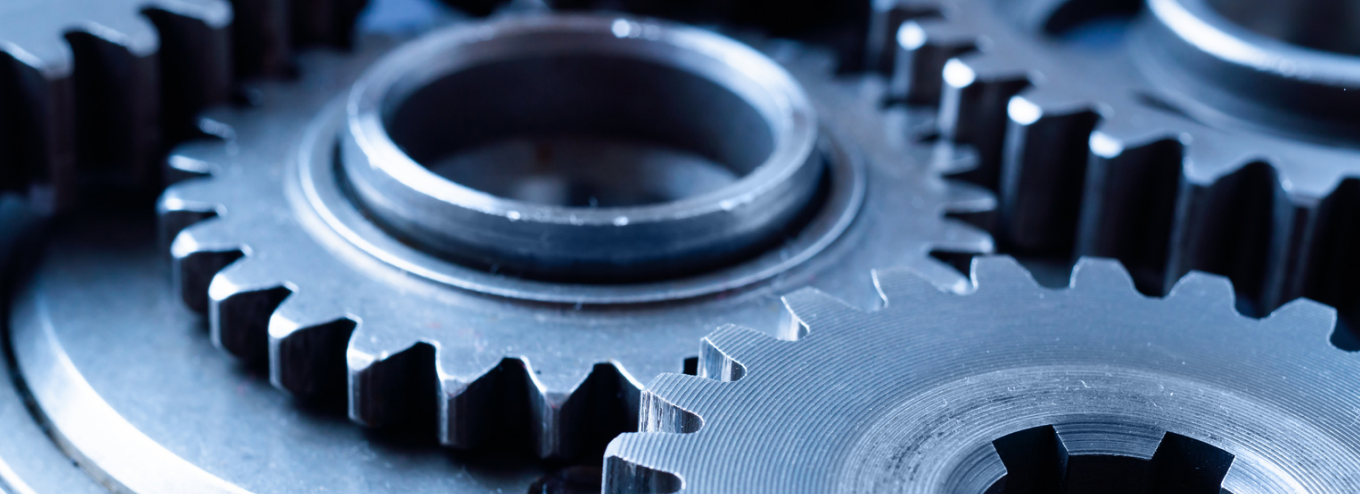
During this time, Medidee has supported Natural Cycles in various **projects within the Quality-Regulatory-Clinical realm**, such as:

- Support during the **creation and implementation of the QMS**, with the review of several Standard Operation Procedures
- **Organization of company training** which aimed to build internal expertise on the requirements and implementation of relevant standards (e.g., IEC 62304 on software lifecycle processes)
- Regular service for **QMS audit as per ISO13485, MDR and QSR**
- **Revision of parts of Technical Documentation**, including risk analysis

One of our latest collaboration projects pertained to the creation of an **MDR-compliant Clinical Evaluation file**, offering crucial support to the company to confront the increased requirements under MDR. This project was executed in two parts, whereby a **two-day Clinical Evaluation training** was first organized.

Subsequently, a copiloting process was initiated, during which frequent meetings took place between Medidee and Natural Cycles to discuss and define **strategic and methodological aspects of the Clinical Evaluation Plan and Report**, such as:

- Definition of a state-of-the-art **literature search strategy**, compliant with the requirements of MEDDEV 2.7/1 rev 4
- **Description of the relevant state of the art** as outcome of the search and appraisal of the retrieved publications



- Definition of **relevant safety and performance parameters** from the state of the art that were used as reference for comparison

- Definition of the appropriate **clinical evaluation strategy** as per Article 61 of the MDR

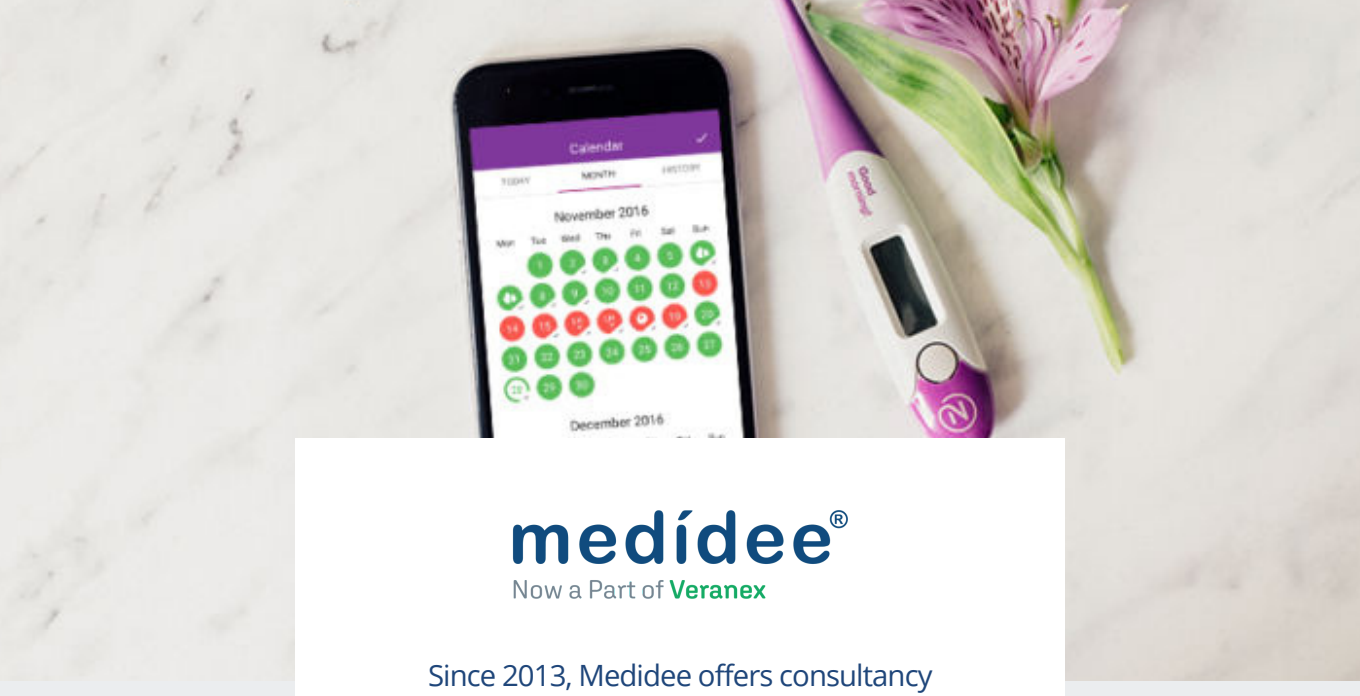
- **Analysis and appraisal of all preclinical and clinical data** with conclusion on their sufficiency to demonstrate the performance and safety of Natural Cycles and compliance to the relevant General Safety and Performance Requirements of Annex I of the MDR.

RESULTS ACHIEVED

This copiloting process was concluded with a complete document review from Medidee's Clinical Evaluation team.

The finalized Clinical Evaluation file was submitted to the Notified Body (TÜV SÜD) and was approved in March 2022, making Natural Cycles the **first and only contraceptive app certified under MDR**.

> When embarking on our journey through evolving regulatory frameworks, Medidee was a stable, informative resource. The experienced team explained detailed guidelines and closely coached us to the point of submission, where the outcome was positive.
>
> **Dr Jack Pearson, Medical Affairs Manager at Natural Cycles**



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We are ISO 13485 & ISO 9001 certified.

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