



EC DECLARATION OF CONFORMITY

Name of the Manufacturer: NaturalCycles Nordic AB

Address of the Manufacturer: Luntmakargatan 26, 111 37 Stockholm, Sweden

Unique ID of Product: NaturalCyclesUID00001

Marketing name of product: Natural Cycles

Medical Device Version: B

App Version: 3.0 and onwards

Intended use: Natural Cycles is a stand-alone software application intended to monitor a woman's fertility and can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).

Classification:

Name	Unique ID	Class	Reference	Rule
Natural Cycles	NaturalCyclesUID00001	Class IIb	MDD 93/42 Annex II	Rule 14

Declaration of conformity:

NaturalCycles Nordic AB is solely responsible to issue this declaration that this product meets all applicable requirements of the European Directive 93/42. Applicable harmonized standards have been used to demonstrate safety and efficacy of the device when used according to the Instructions for Use.

The following standards were applied:

Quality Management System: EN ISO 13485:2016


Risk Management: EN ISO 14971:2007

Software LifeCycle EN 62304:2006

TÜV SÜD Product GmbH is Notified Body with identification number 0123.
Ridlerstrasse 65, 80339 München, Germany

This Declaration of Conformity is valid for 1 year from the signing date.

Stockholm 29 May 2018



Dr. Raoul Scherwitzl, CEO