

## AC Declaration of conformity

<b>Document title</b>	AC Declaration of conformity
<b>Version</b>	19
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### 1. Asthma Calculator Declaration of Conformity

The Asthma Calculator is a software library, intended to be used for calculation of analytical results relevant for asthma diagnosis and treatment, based on PEF measurement results.

The Asthma Calculator has been developed, produced and tested within a quality management system according to ISO 13485:2016 and Medical Devices Regulation (EU) 2017/745. The quality management system is certified by SGS Fimko Oy, notified body number 0598.

#### 1.1. Name and address of the manufacturer

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Single Registration Number: FI-MF-000041810

This declaration of conformity is issued under the sole responsibility of the manufacturer.

## 1.2. Object of the declaration

Asthma Calculator

Version 1.1.0

Basic UDI-DI: 6429811352AC\_01ZL

## 1.3. Product classification as in Annex VIII

### **Medical Device Class: IIa**

Classification based on MDR Annex VIII, Chapter 3, paragraph 6, Rule 11.

## 1.4. The object of the declaration described is in conformity with the relevant Union harmonization legislation

Medical Devices Regulation (EU) 2017/745, Annex IX (Quality Management System Assessment and Assessment of Technical Documentation section 4)

## 1.5. References to the relevant common specifications and harmonized standards used

- EN ISO 13485:2016 + AC:2018 + A11:2021
- EN ISO 14971:2019 + A11:2021
- EN IEC 62304:2006 +A1:2015
- EN IEC 62366-1:2015

## 1.6. Certificates

### 1.6.1. EU Quality Mangement System Certificate

Certificate No. FI26/00000014

Issue 1

Valid from 05 February 2026 until 04 February 2029

### 1.6.2. EU Technical Documentation Assessment Certificate

Certificate No. FI26/00000015

Issue 1

Valid from 06 February 2026 until 05 February 2029

## 1.7. Notified body information

SGS Fimko Oy  
Takomotie 8  
00380 HELSINKI  
Finland

Notified Body number: 0598

### **Signed electronically on behalf of Orla DTx Oy,**

Tuomas Mäkynen, CEO

Oskari Koskimies, PRRC

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