

Instructions for Use EvidaMed

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EvidaMed is in conformity with Regulation (EU) 2017/745 on medical devices (MDR).

Please read all instructions before use.



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Contents

1	Abbreviations and Definitions of Terms	3
2	Intended Use	3
3	Indications	3
4	Contraindications	3
5	Patient Target Group	3
6	Intended Users	4
7	Use Environment	4
8	Warnings and Precautions	4
8.1	For Patients	4
8.2	For Healthcare Professionals.....	4
9	Overview of Operating Elements, Components and Setup	4
10	Operating Instructions	5
11	Clinical Benefits	5
12	Information on Software Including Cybersecurity	5
13	Support Information	6
14	Symbols Glossary	6

1 Abbreviations and Definitions of Terms

Term	Definition
HCP	Health Care Professional
COPD	Chronic Obstructive Pneumonal Disease
CHF	Chronic Heart Failure
IBD	Inflammatory Bowel Disease

2 Intended Use

EvidaMed is a remote patient monitoring software solution intended to supplement standard patient care by providing healthcare professionals (HCPs) with a means to remotely support patient management. It is intended to facilitate proactive patient management, enhance patient engagement, and provide valuable data for treatment progress tracking. The software facilitates risk assessment based on user-defined parameters and the software or the manufacturer do not validate the efficacy of those parameters.

The software is not intended as a replacement for regular clinical examinations, face-to-face consultations, or established best practices in patient management. EvidaMed's intended purpose is to provide supplementary risk information to support ongoing patient care and inform adjustments to patient treatment plans, as determined by the prescribing HCP.

3 Indications

Any chronic disease for which patient-monitoring algorithms exist or can be defined. Currently, the diseases to be implemented are:

- COPD
- Asthma
- CHF
- IBD

4 Contraindications

Conditions which prohibit the correct use of the patient app, for example:

- Cognitively or visually impaired patients
- Patients with mental issues inhibiting the correct use of the app

The HCP prescribing the app should always check whether the patient is able and willing to electronically answer health related questions.

5 Patient Target Group

The product can only be prescribed to patients who have access to a state-of-the-art mobile phone (iOS or Android) where they can install the patient app. Also, patients, or a caregiver, need to be able to reliably operate their mobile phone, e. g. the product might not be suitable for visually or cognitively impaired patients. Otherwise, the patient population is not limited.

6 Intended Users

The web app for health care professionals is to be used by trained HCPs only. The mobile app is used by patients only.

7 Use Environment

No specific limitations. The product is intended for home use by patients. Health care professionals will use the product in medical practices or hospital offices.

8 Warnings and Precautions

8.1 For Patients

- In case of medical emergencies, contact a doctor or emergency services immediately.
- Contact a healthcare professional if you feel uncertain or if your health deteriorates.
- Always answer the questions within EvidaMed truthfully.
- If you are using the app on behalf of another patient, you must ensure that the patient's information is transmitted and not your own.

8.2 For Healthcare Professionals

- Check your patient's health status actively in EvidaMed daily. You will not receive any notification if there is a high risk that your patient's health is deteriorating.
- Educate your patients carefully about EvidaMed and its intended use.
- Call your patient immediately if you think that the patients' health has deteriorated.
- The system does not replace regular clinical examinations, face-to-face consultations, or established best practices in patient management.
- Please check patients' personal data stored, such as age and gender, before using EvidaMed.
- Before prescribing a questionnaire, verify its content and how it is evaluated and make sure it fits to the patient's indication.

9 Overview of Operating Elements, Components and Setup

The system consists of a mobile app to be used by patients, a web app for HCP accessible over Internet (every HCP has personal user credentials) and a Secure Backend Infrastructure in between the two frontend apps, responsible for the secure processing of information entered by patient and HCP.

Patient mobile app can be downloaded for free from Google Play or Apple App store. A personal invitation code is needed to complete registration. After registration patients can use the app to regularly fill in and submit health questionnaires.

To access the HCP web app healthcare providers, need to request an account for their organization with associated users for all HCPs intended to use the system. After setting their personal user credentials HCPs can use the system can be used on any state-of-the-art computer with a monitor and running internet connection.

Secure backend infrastructure processes health journal entries in-time using risk-based assessment and updates monitoring data. This data will then be visible in the HCP web app. The backend application ensures that HCPs only see data for patients associated with their organization.

10 Operating Instructions

The following illustration shows what HCPs and Patient need to do to establish monitoring loop.

Nr	HCP	Patient
1	Log into EvidaMed HCP WebApp using personal credentials	
2	Enter patient's personal information	
3	Invite patient to use EvidaMed	
4	Prescribe health questionnaires to be answered	
5		Check per inbox for invitation email containing personal registration code
6		Download EvidaMed app from respective app store
7		Register for app usage by entering personal registration code and create login
8		Answer and submit health questionnaires on a regular basis
9	Check patients' health status daily	
10	Call high risk patients for deterioration and reassess their health status	
11	Decide on further procedure after personal reassessment of the patient's health status	
12	Log additional information on patient's health or treatment in EvidaMed and primary system	

11 Clinical Benefits

Clinical benefits of the device are the correct implementation of monitoring algorithms which are preexisting accepted algorithms or defined by independent doctor's groups (which itself have a direct clinical benefit). As such, the clinical benefit of the device is only measurable through its correct function.

12 Information on Software Including Cybersecurity

To ensure the confidentiality of information processed by the software, weak passwords are strictly to be avoided. The software enforces a password policy that requires a minimum length of at least 8 characters, including the use of both uppercase and lowercase characters, at least one numeric digit,

and at least one special character. This policy is intended to reduce the risk of unauthorized access and to strengthen overall cybersecurity.

13 Support Information

Contact Information Distributor: AD Swiss Net AG
Seidenstrasse 4
CH- 8304 Wallisellen
E-Mail: evidamed@ad-swiss.ch
Web: <https://www.ad-swiss.ch/contact>

Note to patient and/or user of the device:

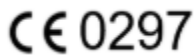
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Contact Information Manufacturer: Effectum Medical AG
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CH-4600 Olten
E-Mail: support@effectummedical.com
Web: www.effectummedical.com

14 Symbols Glossary



Medical Device



CE marking by Notified Body 0297 (DQS Germany)



Article Number of Software



Software Version



Release Date of Software Version



Consult instructions for use or consults electronic instructions for use



Unique Device Identified, combined of UDI-DI (01) and software version (21)



Legal Manufacturer



European Representative
