


MDSW	Information about safety Rev. 01 del 25/10/2023	
-------------	-----------------------------------------------------------	------------------------------------------------------------------------------------

Information about the Safety of the Medical Device ADiLife model 0118.

General Description of the Device

ADiLife model 0118 is a medical device software based on a telemedicine computing platform that enables the sharing and analysis of information between patients and healthcare providers or healthcare facilities responsible for managing the patients. The platform is designed to be used for the treatment of a wide range of conditions, including but not limited to: diabetes, COPD, cardiac, gastroenterological, oncological, ALS, SMA, etc...

The sharing of information is initiated by patients through the use of a mobile application, while healthcare providers exchange information with patients by interacting through the web portal.

The information that patients can share includes:

1. Physiological parameters acquired through a variety of monitoring medical devices that communicate with the mobile component.
2. Responses to customized questionnaires based on the specific medical conditions.

Healthcare providers, on the other hand, can input through the web portal a variety of patient health information and documents, including medical history, clinical reports, etc..., as well as specific thresholds for monitored physiological parameters, set according to the patient's health status and specific medical conditions. Healthcare providers can also input specific reminders that assist in the utilization of measurements and adherence to the treatment plan.

Furthermore, the platform is capable of generating events that support patient management, minimizing the risks of exacerbation of conditions, such as:

1. Events exceeding the thresholds related to measurements.
2. Events of missed measurement of a physiological parameter.
3. Events of missed feedback regarding a reminder/drug administration.

Intended Users

- Patients with various medical conditions, general practitioners, specialists, and clinicians.
- Patients who independently choose to monitor physiological processes.
- Patients selected by healthcare companies for remote assistance.

Intended Use

The collection and analysis of data and information are aimed at supporting healthcare personnel in making diagnostic or therapeutic decisions.

Warnings


The medical device is intended to be used exclusively with third-party medical devices that have been internally validated (the complete list is provided in the user manual). The use of ADiLife by anyone other than the intended users, for any purpose or application other than specified in the manual, or the failure to adhere to any of the instructions, will be considered **IMPROPER USE**.

Before using the medical device, it is mandatory to read this instruction manual. The proper functioning and full compliance of the device are strictly dependent on the application of all the instructions contained in this manual.

In case of any inconvenience or malfunction of the medical device, do not hesitate to contact the support service:

- Phone: +39 071 2901262
- Email: support@adilife.net

ADiLife srl

MDSW	Information about safety Rev. 01 del 25/10/2023	
-------------	-----------------------------------------------------------	-------------------------------------------------------------------------------------

Contraindications

The use of the device has no contraindications for patient safety as it does not alter their health conditions but records measurements of third-party physiological processes and makes them available to healthcare personnel.

Device Safety

Based on the risk assessment conducted in accordance with UNI EN ISO 14971 and IEC 62304 standards, it is evident that the ADiLife model 0118 Software Medical Device is a SAFE DEVICE because:

- **It does not present unacceptable risks to users.**
- **It has an overall low level of risk.**
- **It belongs to risk class A.**

Cyber security

Access to the platform is protected by credential verification based on username/password. The system ensures that the password is effective (minimum 8 characters, including uppercase and lowercase letters, at least one number, and one special character).

Users must not share access credentials with others to prevent unauthorized access to the system.

Personal Data Security

Access to the platform is protected by credential verification based on username/password.

ADiLife Srl, through the use of the software, will collect health data voluntarily provided by the user in their interactions. This will occur exclusively with their prior consent or at their direction and solely for the purposes outlined in the Privacy Policy, which can be directly viewed from the “App” and on the website <http://www.adilife.net>.

ADiLife srl

Sede legale: Via Mosca, 52 – 00142 Roma – Tel. + 39 06 51607174 Fax: +39 065137499
Sede operativa: Via Valenti, 2 – 60131 Ancona – Tel. + 39 0712901262 Fax: +39 0712917195
Cap. Soc. € 259.160,00 i.v. – Registro imprese di Roma – R.E.A. n° 1540081 – C.F./P.IVA 14694481004
E-mail: info@adilife.net – www.adilife.net