

Derma2go
Instructions for Use

**LET'S RESHAPE THE
FUTURE OF
DERMATOLOGY
TOGETHER.**

Derma2go – Your online dermatologist!

1.

Take and upload photos of your skin problem

Take photos of the affected areas of your skin, preferably using your smartphone, from several angles and distances. Make sure the resolution is good before uploading the photos to our secure server.



2.

Fill out a short medical questionnaire

Please fill out the short medical questionnaire completely. This will take approximately 3 minutes.



3.

Register for your secure patient account

Once you register, you will have access to your secure patient account, where you can view your skin diagnosis and individual treatment plan at any time.



Derma2go
Information about the
Medical Device

**LET'S RESHAPE THE
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Product and Manufacturer



Derma2go is a medical device classified as Risk Class IIa according to Rule 11 of EU Regulation 2017/745 (MDR)



UDI-DI: 04260676710450
EMDN: Z12040192

Software Version: See Apple AppStore (iOS)/Google PlayStore (Android)/Web application



Distributor: derma2go Deutschland GmbH,
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info@derma2go.com, www.derma2go.com



Swiss authorized Representative:
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Manufacturer: be-on-market GmbH, Lilienstraße 33, D-91244
Reichenschwand, info@be-on-quality.com, +49 9123 1529250

All trademarks named and shown are trademarks of the respective proprietor and are recognized as being protected. Reprinting, translation and duplication – even of excerpts – require the written permission of the manufacturer.

A free paper form of the instructions for use is available upon request within 1 week. Please contact info@derma2go.com.



CAUTION: Photo Upload

Upload at least 1 photo, preferably 3 or more, if possible.

Take at least 1 overview photo and 2-3 close-up photos

Take the photos against a light background.

Make sure that the photos are not blurred.

A photo may have a maximum size of 10 MB.

Usually, a maximum of 5 photos can be uploaded.

Please also note the illustrations shown for taking an overview picture!



CAUTION : Description Text

Describe your current skin problem in as much detail as possible!



CAUTION : Questionnaire

Fill out the associated questionnaire completely and in as much detail as possible!



CAUTION: Disclaimers

Any diagnostic and/or therapeutic decisions are made exclusively by medical professionals. The product itself (derma2go) does not interfere with these diagnostic or therapeutic decisions made by medical professionals and does not provide any interpretative information.

Do not use in acute life-threatening situations.

A diagnosis cannot be made if the quality of the photos and information provided by the patient is insufficient/inadequate.

Teledermatological procedures must not be performed if the patient's personal presence appears to be necessary (e.g., the affected area cannot be adequately photographed due to hair, mucous membrane, or skin color; if a full-body examination is required; in the case of pigmented lesions that require dermatoscopic examination).

Teledermatological procedures may not be performed if the patient is unable to use the platform/app or to consent to it, e. g. because of mental/cognitive/language impairments. In this case, the patient may be able to use the platform/app with help/support from another person.



CAUTION: Contraindications

All non-dermatological/non-allergic indications

Acute life-threatening situations

CAUTION : Side Effects

None

IMPORTANT

If a serious incident or undesirable side effects not mentioned in these instructions for use occur during the handling and use of the product, please report these to the manufacturer (be-on-market GmbH) and the competent authority, providing a detailed description of the incident or side effects.

Intended Purpose: Derma2go is a software as a medical device that offers dermatological telemedical services. It supports structured, asynchronous communication between users (including patients) and dermatologists (specialized medical doctors). This includes the possibility to send medical enquiries to the dermatologists by choosing a price plan (if applicable), uploading photos and answering medical questionnaires (that can be adapted by the institution/dermatologist and include dynamic functions). The dermatologists can answer these enquiries, possibly including a suspected diagnosis and prescription. The users can order the prescribed medication and can request follow-up consultations.

Intended Patient Population: The use of derma2go is not restricted to any patient population. Patients that are unable to use derma2go on their own (e. g. children, elderly or disabled persons) might use it with help or support from others.

Intended Users in the medical context of use:

Patients (lay person; this includes lay persons using the product on behalf of the patient), Dermatologists (medical doctor/healthcare professional), Referring doctors/pharmacies (medical doctor/healthcare professional), Technical support (lay person)

Note: Lay person means an individual who does not have formal education in a relevant field of healthcare or medical discipline.

Intended Users in the non-medical context of use: Secretary (lay person), Biller (lay person)

Medical Indications: Dermatological clinical pictures/(potential) pathologies, changes to the entire human skin; these conditions are covered by the following ICD-10 codes: L00-L99 Diseases of the skin and subcutaneous tissue, R21 Rash and other nonspecific skin eruption, R22 Localized swelling, mass and lump of skin and subcutaneous tissue

Contraindications: All non-dermatological/non-allergic indications, acute life-threatening situations

Intended Use:

derma2go is intended to be used on a mobile device (e. g. smartphone) or stationary device (e. g. PC) and can be used in any environment, including domestic environments, outdoor environments, medical offices and pharmacies.

To ensure a sufficient quality of the photos used for the diagnosis, it is recommended to make sure there is sufficient light when taking the photos. Depending on the case of application, it is advisable to choose an environment that guarantees sufficient privacy.

derma2go is normally intended for continuous use for less than 60 minutes (transient use). The frequency of use is not limited. As derma2go is software only, it is not invasive and there is not body contact.

Claims:

Clinical Performance:

- Derma2go enables diagnoses made by doctors on the basis of image material with >85% agreement with specialist diagnoses on site (diagnostic concordance)
- Derma2go enables diagnosis and treatment without a doctor's appointment (thus avoiding visits to the doctor) in an average of 79% of cases
- In 98.15% of cases, patient concerns can be partially (12.50%) or completely (85,65%) resolved via derma2go from the doctors' point of view
- In 90.50% of cases, patient concerns can be partially (24.70%) or completely (65.80%) resolved via derma2go from the patients' point of view

Patient Benefits:

- Quick diagnosis (usually possible within 24 hours)
- Reducing the time it takes for patients to see a doctor and receive a diagnosis
- Access to dermatologists even in more rural regions

Non-Clinical Claims: Fully GDPR-compliant and protected by state-of-the-art security measures.

Installation: Derma2go is available as a mobile app for iOS (iPhone) via Apple AppStore and for Android via Google PlayStore. The app is installed automatically after downloading it. The app can be downloaded and installed by the user him-/herself. An internet connection is required to download and install the app.

The web application can be accessed via web browser. An internet connection is required.



CAUTION: Compatibility Requirements

derma2go Mobile App:

- iOS 18 or higher is required
- Android 10 or higher is required

The derma2go web application is compatible with all common web browsers.

Maintenance: Derma2go is maintained through regular updates that are provided directly through the Apple AppStore/Google PlayStore or directly in the web application.

The expected lifetime of the product is estimated to 2 years. The expected lifetime is tied to factors such as active maintenance (e.g., updates, vulnerability scanning, patch support), market relevance (including clinical benefit), compatibility with host environments and ongoing acceptability of the benefit-risk ratio.

Deletion: The mobile application can be uninstalled on the mobile device.

The web application does not have to be uninstalled, as it is not installed locally on the device.

Data Security and Privacy: For information on data security and privacy, please see: <https://www.derma2go.com/en/data-privacy>

For **Support** contact:
support@derma2go.com.

Labeling



Manufacturer name and address



CH REP
Swiss authorized representative



Warning

(Warnings have their origin in risk assessment. They are necessary to draw the user's attention to residual risks or sources of danger.)



Distributor name and address



Medical Device Symbol – Indicates that the product in question is a medical device



If the inspection of the accompanying documents is a binding act, this safety label must be used.

The inspection of the accompanying documents is a binding act because the IFU contains information that serves as a primary risk control measure according to the risk analysis.



CE label

(for Class II/III products, the quarter-digit identification number of the Notified Body involved must be indicated)



UDI Symbol

Displays a carrier containing information about a unique product identification