myoncare

App Guidelines for Use - myoncare v.1.13

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- **Device name/ trade name:** myoncare
- **Version:** 1.13
- **FDA code:** Medical Device Data System, product code OUG, Class I medical device, 510(k). The FDA has recommended enforcement discretion for this device.
- **IFU Release date:** 2025-10-13

MD $C\epsilon$ **0123**   **Rx only**

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If you require a printed version of the instructions for use, please contact us via email at service@myoncare.com. You will receive it within 7 working days.

Do you need further assistance, feedback or further questions? Feel free to reach out:

- By submitting a ticket from the Profile Menu in PatientApp or PWA.
- By email service@myoncare.com
- By phone: +49 89 4445 1156
- By our ticketing system:

We treat your data with the utmost diligence. All data will be encrypted, so that no data can be used to identify you as an individual outside of your care team. Regarding data privacy related topics, please refer to our privacy policy or contact the following ONCARE support: privacy@myoncare.com

Table of Contents

1. Symbols

Symbol	Meaning	Symbol	Meaning
⚠️	Warnings	LOT	Lot number
(!)	Precautions	V	Version number
(i)	Information	📖i	Consult instructions for use or consult electronic instructions for use
🏭	Manufacturer	CH | REP	Swiss Authorized Representative
🏭 DE	Country of manufacture The date of manufacture may be added adjacent to this symbol.	CE 0123	CE mark – Indicates that the medical device is CE marked
UDI	Unique Device Identifier	Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
MD	Medical Device		

2. Device Description

Mobile consists of two versions:

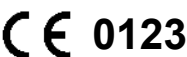- **PatientApp** is a mobile application that can be downloaded from the iOS or Android application stores and installed on a mobile device.
- **Progressive Web Application (PWA)** is a web version of PatientApp that users can access through a link and open directly in the browser of a handheld device or workstation.

Mobile can only be used in conjunction with a healthcare professional using Careplan Manager.

2.1. Intended purpose

Mobile: to give the patient a portal to their data and means of communication and engagement with healthcare professionals. This service allows the patient to comply with Caretasks, medications and appointments that were designed, assigned and scheduled for them by the healthcare professionals. In addition, this service allows the patient to communicate via texting, document sharing and video consultations.

myoncare non-medical for patients shall be a portal to communicate and share/ transfer information with the healthcare professionals, simultaneously enabling them to respond to elements provided by them.

2.2. Intended user

The intended users of Mobile are patients aged 18 years and older, except patients affected by the contraindications.

2.3. Intended patient population

The intended patient population of Mobile are patients aged 18 years and older, except patients affected by the contraindications.

The product variant is determined by the product your medical professional is using.

ONCARE does not specify any intended patient population for using the non-medical variant.

2.4. Place of use

Mobile: places of use can be in a clinical or non-clinical setting.

Mobile can be used throughout the day by the patients given that natural or artificial illumination is provided and through browsers or app on handheld devices.

2.5. Indications for use

myoncare (Careplan Manager) provides a system for caretask management, which also allows customization of the scoring of Caretask components according to the healthcare professional's requirements within the specifications of the system. The validation and scope of myoncare (Careplan Manager) includes the Caretask management and the scoring system as well as the associated notification system. It is designed to provide flexibility to your healthcare professional in monitoring the health condition of patients by allowing the healthcare professional to choose the content of Caretasks.

Therefore, use of Caretasks for various indications, which may be distributed over multiple medical specialties, except the ones listed in the contraindications, is possible at the healthcare professional's discretion.

However, the content of these Caretasks is not controlled or validated by myoncare (Careplan Manager).

2.6. Warnings

- Do not use myoncare (Mobile) if you suffer from a disease or condition affecting the central nervous system or if you are unfit to use hand-held devices unsupervised due to physical or mental disability.
- DO BY NO MEANS USE MYONCARE IN EMERGENCY SITUATIONS. CONTACT A HEALTHCARE PROFESSIONAL IN CASE OF EMERGENCIES. MYONCARE (MOBILE) DOES NOT REPLACE A FACE-TOFACE DIAGNOSIS/ ANAMNESIS.
- Your healthcare professional is not obliged to monitor your health parameters transferred from your device. In case of doubts, worries or emergencies please contact your healthcare professional directly.
- IF YOU HAVE OR SUSPECT THAT YOU HAVE A MEDICAL PROBLEM OR CONDITION, PLEASE CONTACT QUALIFIED HEALTH CARE PROFESSIONAL IMMEDIATELY.
- We advise users of Mobile to always seek the advice of a physician or other qualified health care provider with any questions regarding personal health or medical conditions. The Caretasks or Care Pathways are not intended to be a substitute for professional medical advice, diagnosis or treatment.
- If you are connected to myoncare WebApp during an update, you will temporarily not be able to use Mobile for technical reasons. You will be notified about this after logging in. ONCARE GmbH will proactively update the designated contact person for each customer regarding the anticipated update schedule.
- Make sure to support healthcare professionals by truthfully replying to the content, which was provided to you to optimize the success of your treatment!

2.7. Precautions

- We highly recommend ensuring a working internet connection at least once every 24 hours for proper synchronization to prevent a caretask occurrence is overseen.

2.8. Contraindications

- Mobile shall not be used for patients whose central nervous system is affected by any disease or condition which results in them being unfit to use hand-held devices unsupervised due to physical or mental disability. Mobile shall also not be used if any other disease or condition leads to a patient's physical or mental unfitness to use hand-held devices unsupervised.
- You must be 18 years or older to use Mobile as a medical device.
- Mobile is not intended to be used in emergency situations.

2.9. Undesirable side effects

No undesirable side-effects are expected or identified (based on the identified clinical data) from the use of Mobile. The application of myoncare in the clinical routine depends on the clinical content generated by Healthcare professionals and the responses given by the patients. Patients trying to "trick" the system by providing erratic responses in an attempt to under-/ overreport their actual condition depend on their integrity and cannot be prevented from a manufacturer/ technical point of view.

3. Technical Requirements

3.1. Update

When a new version of Mobile becomes available, PatientApp users will receive a push notification informing them about update on the Appstore. For the Progressive Web App (PWA), updates will automatically occur as users refresh the application page within their web browser.

The ONCARE GmbH does not support backwards compatibility. To guarantee the best user experience, it is mandatory to update Mobile to the most up to date version of it.

If any of your connected Careteams is updating myoncare to the latest version, you will temporarily not be able to use Mobile for technical reasons. You'll be notified about this after logging in.

To enhance the quality of Mobile and provide assistance to end users, the following information is monitored:

- User session start time after successful login in Mobile.
- Errors encountered within Mobile during user sessions.

3.2. Compatibility with other (medical) devices

myoncare Careplan Manager does not claim to be compatible to any other (non-)medical devices or any of their accessories available on any worldwide market other than myoncare Mobile.

The compatibility of myoncare Careplan Manager is always ensured by parallel development, verification, and validation.

3.3. Browser compatibility

Mobile PatientApp requires iOS 13 (or higher) or Android 12.0 (or higher). Please make sure your operating system software is always up to date or at least within the required specifications.

Mobile PWA additionally requires end users (i.e., patients) to use Windows 10 (or higher) or MacOS 10.11 (or higher) if using Mobile on computer desktops in order to function as intended. For optimal user experience, it is recommended to use either Safari 14.0 or higher or Chrome 90 or higher as a web browser.

The use of myoncare has been verified using officially released versions of mobile device operating system software. Testing software versions are not supported.

3.4. e-IFU Technical Requirements

Refer to Section 3.3 for the information on the technical requirements to view the e-IFU.

3.5. Supported languages

Language allows you to choose the language of Mobile. This setting only affects the language of the Mobile including the date formats, but not the content that is provided to you by the respective Careteam. The following date formats are used:

- DE: DD-Month-YYYY
- EN: Month-DD-YYYY
- IT: DD-Month-YYYY
- PT: DD-Month-YYYY
- FR: DD-Month-YYYY
- AR: YYYY-Month-DD

Note: After switching to Arabic, the text and icons alignment in the Mobile will be from right to left. This change is to accommodate the right-to-left (RTL) reading direction of the Arabic language and ensures a culturally appropriate user experience for Arabic-speaking users.

Note: Even when switched to the Arabic language, Mobile still uses Latin numbers and Gregorian calendar dates.

4. Mode of use

QR Codes

QR codes are essential elements for interacting within myoncare. They provide users with the capability to register as new patients or access new Caretasks and Care Pathways. By scanning the QR code, users can initiate these actions, enabling experience within the platform.

Deeplinks

A Deeplink is a hyperlink associated with a specific new patient registration letter, Caretask, or Care Pathway, offering an alternative to QR codes. It can be accessed on both mobile and desktop devices without the need for any application installations.

When a user clicks on a patient registration letter deeplink, they are instantly directed to the PWA new patient registration workflow.

When a user clicks on a Caretask or Care Pathway deeplink, they are redirected to the PWA or the PatientApp if it is installed. However, the Caretask or Care Pathway will remain inaccessible until the patient creates an account. Only after successfully creating an account and providing all necessary consents they can access and begin completing their Caretasks or Care Pathways.

Setup & Login

After the installation of PatientApp or opening the PWA link, you will see a login screen. In that screen you can choose between logging in via an already existing myoncare account to access all your health data in myoncare or to register a new account via clicking 'Create Account'.

You have received either a new patient registration letter or a specific QR code for a Caretask (questionnaires/ tasks) or Care Pathway (scheduled questionnaires/ tasks) from your Careteam to connect to the facility.

- **PWA account creation with new Patient registration letter**

Scan the QR code or open the Deeplink to begin registration. You'll see a consent screen and may answer additional questions. Enter the 4-digit password from your letter, verify personal data, and provide an email, password, and an OTP to complete setup.

- **PWA account creation with Caretask or Care Pathway**

Scan the QR code or open Deeplink after viewing the consent screen and answering questions, you can create an account by providing your email, password, and OTP

- **PatientApp account creation with New Patient Registration Letter**

Scan the QR code to start registration. You will see a consent screen, may answer additional questions, and must enter the 4-digit password from your letter. Verify your data and set up your account with an email, password, and OTP.

- **PatientApp account creation with Caretask or Care Pathway**

Scan the QR code, view the consent screen, answer questions, and enter personal details (name, birthday, gender). Complete the setup by providing an email, password, and OTP

When accessing the platform through QR code, deeplink, or the Progressive Web App (PWA), patients are shown an **install banner** that makes it easier to download and access the PatientApp directly from their device. The banner displays a short message ("Use the app for easier access!"), an **Install app** button, and a **dismiss (X)** icon in the top-right corner.

- On **iOS devices**, tapping the **Install app** button redirects patients to the Apple App Store with the correct app page.

- On **Android devices**, the button redirects patients to the Google Play Store with the correct app page.

Patients can dismiss the banner by pressing the **X** icon, after which the banner will no longer appear on their device.

Note: After logging into the PatientApp or the Progressive Web App (PWA), you can customize your security settings. You may choose only one login method by toggling the desired option from the Security section, available options are 2-Factor Authentication (2FA), or Security PIN).

Once you have created an account and are logged in, you cannot change or adjust your email address. However, you can modify your other personal information. The personal information, which is shared with your Careteam, can be adjusted by you via Mobile. A healthcare professional can edit your personal data on their side, but these changes will not be reflected on Mobile.

Furthermore, make sure to allow Mobile to send you push notifications to optimize the functionality and get the best user experience (PatientApp will ask you for this option automatically). However, for PWA, an email will be sent to the patients instead of a notification. All your data is end-to-end encrypted. YOU decide whom you share it with! Refer to the privacy policy for details.

Note: By uninstalling PatientApp or closing Progressive Web Application tab in the browser before you finish the account creation process, you will not be able to register again using the same QR code. Therefore, contact your Careteam to receive a new QR code, which you could use to register as a new patient.

During the process of creating an account, the fields marked with an asterisk (*) are mandatory.

When clicking 'Scan code', Mobile will ask for permission to access your camera. Mobile requires this mandatory permission to enable you to scan QR codes and connect to Careteams.

Please enter all information correctly, the information as well as your profile picture, will be shared with your Careteam and will be used to identify you.

Camera access will also be required for video calls and taking pictures once you want to message them to Careteam, through the PatientApp (this function is not available in the PWA).

Security settings

myoncare wants to secure that your data is safe from unauthorized access. Therefore, you will be logged out after being inactive for 15 minutes. After that, you will have to enter your credentials again to access your health data.

To provide you with the possibility to access your data easier without entering your password every time, you can set up a 4-digit PIN within the profile section within 'Security'. In this way every time you open the application you can access your data by entering the PIN.

Your News section

Your News functionality in the Progressive Web Application and PatientApp allows healthcare professionals to share important updates, health news, and educational content directly with you. While this functionality may usually include links to social media posts for additional context or resources, it is not dependent on social media for content delivery. Instead, its primary focus is to provide high-value information tailored to your needs, helping you stay engaged and connected to your healthcare journey.

Patients Activity Tracking

The activity tracking functionality collects patient actions into Mobile (PWA and PatientApp), including screen visits, button clicks, and the submission of caretasks. This data is then securely transmitted to ONCARE for further comprehensive analytics in order to improve the user experience of Mobile.

The tracking becomes active only when patients check the respective checkbox on the consent screen. Patients have the flexibility to deactivate this feature at any time through the 'Profile -> Activity Tracking' menu in the PatientApp or PWA.

Privacy policy

Your Careteam has the opportunity to provide you with their personal privacy policy. For connecting successfully with your Careteam, you are required to agree to their privacy policy (if available). Only after accepting the privacy policy, is the Careteam allowed to send you information, messages and other content. The privacy policy that you agreed to is automatically saved in your files under the files segment. You have access to them at any time.

By revoking your Careteam's privacy policy, you remove it from your Careteams list.

Note: You will only be connected to your Careteam if you agree to all provided consents. If one of these consents is revoked, a connection to your Careteam will not be possible.

Home screen

	Home tab consists of two primary sections: 1. **Your News Section**: this section includes links to social media platforms that offer you educational content and health updates. Clicking on a link will redirect you to the corresponding social media platform. 2. **Caretasks Section**: this section provides a summary of open caretasks scheduled for the current day and the following two days. By clicking on a task, you will be redirected to its details, where you can complete the required steps. Caretasks can consist of questionnaires, instructions or information provided by the connected Careteams (healthcare professionals) to assess your health status. Caretasks can contain both optional and mandatory questions. Mandatory questions cannot be skipped and are marked with an asterisk (*).

	By clicking on the respective Caretask, you start the Caretask. Reminders for all Caretasks have validity periods assigned, the so-called "lifespan", which will cause elements to disappear after it has expired, i.e., these can no longer be completed afterwards. When no Caretasks are pending or all Caretasks are completed, the Home screen shows an empty state with an icon and text. If your health data is not connected, a banner appears below the empty state prompting you to connect an app to sync health data; selecting this banner opens the connection flow. If your health data is connected but the Home screen remains empty, a banner appears below the empty state indicating that you can view your health data in the Statistics screen; selecting this banner navigates to Statistics. When Caretasks or health data are available, or if an error occurs, no banner is displayed.
	QR Code: for adding a Careteam or requesting new content (Caretask or Care Pathway) from a site, you can click on the QR code symbol on the top right side of the screen. Whenever you scan a new Careteam (i.e. clinic or doctor's office) with a QR code, a designated contact (most probably the healthcare professional treating you) will be added to your Careteam.
	Medication: indicates the number of medication reminders for you. By clicking the button, you will be redirected to the respective medication tab within the home screen. Your medication plan serves as both a reminder to comply with the prescribed dosage and to provide you with simplified guidance on the timing and frequency. You will see a list of your daily medication through which you can browse and tap individual items for further details. **Medication compliance is a crucial part of your therapy! It enables your healthcare professionals to track your progress and adjust the treatment if needed. For this reason, you will be asked to provide a rationale / justification for skipping medication(s) after you tapped on "skip".** **Make sure to check your reminders regularly!** **Contact your attending healthcare professional with questions regarding medication reminders or if in doubt (e.g. about drug-drug interactions).** **Medication Plans**: It is also possible to scan QR codes for medication plans. When a medication plan is successfully scanned, all previous medication reminders will be stopped, and you will receive reminders only for the medications scheduled in the plan. All your HCP from Careteams will be able to view this list, but they will not be able to modify the medication plan or assign additional medications. You can stop receiving reminders for the current plan by pressing the 'Archive' button. **Note: You will continue to receive medication reminders according to your current active medication plan until the plan is not updated or archived.** **Note: The Mobile has been tested with medication plans containing not more than 10 medications. Scanning performance largely depends on the quality of the QR code in the medication plan and the performance of the mobile device's camera.** **Note: please always consult the pdf or hard copy version of the medication plan as point of truth (especially for what it concerns the notes and any particular indication on when to take and when to stop taking the medications).**
	Appointments: indicates the number of appointments for the day. By clicking the button, you will be redirected to the respective appointment section within the home screen. Clicking on the appointment tile will open a sheet, which displays further information about the specific appointment (i.e. location of the appointment or notes from your Careteam). **An appointment is automatically considered accepted. If you are unable to attend the appointment, please clarify with your doctor personally.** **Contact your attending healthcare professional with questions regarding appointments.**
	Stats: provides an overview of your caretask responses and health data and it is available for both the PatientApp and the Progressive Web App (PWA). If there are no active Caretasks linked to your account, the Stats screen will still remain informative. An engaging background is shown, so the screen does not feel empty or inactive. When health data has not been connected, you will also see a banner at the top of the Stats screen. Tapping this banner will guide you through connecting your health data, giving you access to detailed and personalized insights.

	Caretasks score: in case the HCP activates visibility of caretask, you will see the trends of your caretask answers. Your HCP has determined the score for each of your task answers. After completing the task, your total score will be the sum of the score from each answer. Your total score falls into three categories: green, yellow, and red, each representing different score ranges. **Note: There is no need to worry if you see only red colors. They do not indicate any problems with your health status; they simply reflect your score range defined by your HCP.** **Health data:** you will see your activity data from Google Fit, Apple Health, and Withings, if you have activated this option in "Settings screen" → "Activity Data".
⚫⚫⚫	By clicking this button, a menu will be displayed at the bottom of your screen, consisting of three tabs: All files, Careteam(s) and Settings. • **All Files**: this tab provides access to a list of all files associated with you. You can browse, search, and manage these files directly from this tab. • **Careteam(s)**: this tab displays the Careteams associated with your account. In addition,, the roles of the Careteam members, chat history, notifications for unread chats are also displayed, and allow starting new chats for seamless communication. • **Settings**: this tab allows you to configure your preferences, update your account details, and adjust other customizable options. It serves as the control center for personalizing the application experience.

Careteam screen

👥	• **Careteam: t**apping on the Careteam tab will redirect you to a comprehensive view of all the Careteams associated with your account. Within this tab, you can access detailed information about each Careteam member, including team member names and roles. Additionally, it gathers all chat messages exchanged with the Careteam members, allowing you to review previous chats, start new chats and review notifications for unread chats. A Careteam is a trusted group of people who have access to your medical information. Members of your care team can assign, adjust or create a Caretask or medication reminder. Simultaneously, this serves as your contact list for the (video) chat functionality.
📁	Tappin on this icon at the top right of the chat screen will redirect you to an overview of all files which have been shared between you and the Careteam you are connected to. Types of files which can be shared: • Document types (PDF) • Image (JPEG/ JPG, PNG, GIF, BMP) • Video types (MP4, MOV, M4V) • Audio (WAV, MP3, MP4).

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Tapping on the '+' symbol on the chat bar will allow you to request a video call, share files (e.g. documents, images, videos and audios) or send a photo

When you upload a file or take a photo in **Chat**, you'll see an in-app menu appear at the bottom of the screen. This menu gives you consistent options to either select a file from your device or use your camera. The in-app menu replaces the system pop-ups that used to vary by device, making file uploads and photo capture simple, consistent, and dependable across the app.

If you log out from a Careteam / revoke any Careteam access to your data, you will need either your invitation letter to re-scan your personal QR code or approach a doctor within your care team to generate a new code!

Please refrain from requesting video calls multiple times since this will not expedite your request. Please be aware that your entire Careteam at this site will have access to the files you send.

By revoking the consent of your last or only Careteam your profile will also be deleted and cannot be restored.

All Files screen

📁	**Files:** Tapping on 'All Files' tab provides you an overview of all files which have been shared between you and the Careteams you are connected to. Files can be shared via the chat section or via Caretasks you receive from the healthcare professionals. Healthcare professionals can define if a file that is included within a Caretask shall be stored in your files after you answered the Caretask or if the file is only visible within the Caretask itself. Furthermore, healthcare professionals have the option to provide you with reports of the Caretasks you answered. If a report is generated, you will be informed within the application. The reports will be stored within the files section as well. Reports from Caretasks shall provide you with the possibility to share the information with other healthcare professionals and can provide them with valuable information. **Note: Within the report, only question titles will be shown and therefore it might be that not all the information from the Caretask you answered will be displayed.**
⬆️	Tapping the icon located in the top-right corner of the **'All Files'** screen allows you to share files directly from your mobile device. To do so, press and hold the file you wish to share; this action also enables you to select multiple files if needed. Once selected, you can share the files via other applications on your device. Please note that the maximum file size for sharing is 25 MB at a time.

Settings screen

👤	**Edit Profile** allows you to edit the profile information as well as the profile photo displayed within the application. If you no longer want to keep one, simply remove it directly from your profile settings. This information will be displayed to your connected Careteams, so please ensure that the data is correct. When you update your profile photo, an in-app menu appears at the bottom of the screen. From here, you can choose to take a new photo or select one from your files. This in-app menu replaces the old system pop-ups, giving you a smoother and more reliable experience that works the same way on every device. **Note: You can change all your profile information except your email address, and it is automatically transmitted and displayed to your Careteams. A healthcare professional can edit your personal data on their end, but these changes will not be reflected on your Mobile device.**

Security: allows you to set up a 4-digit-PIN or two-factor authentication.
Languages: allows you to choose the language of Mobile. This setting only affects the language of the Mobile including the date formats, but not the content that is provided to you by the respective Careteam. The following date formats are used: • DE: DD-Month-YYYY • EN: Month-DD-YYYY • IT: DD-Month-YYYY • PT: DD-Month-YYYY • FR: DD-Month-YYYY • AR: YYYY-Month-DD **Note: After switching to Arabic, the text and icons alignment in the Mobile will be from right to left. This change is to accommodate the right-to-left (RTL) reading direction of the Arabic language and ensures a culturally appropriate user experience for Arabic-speaking users.** **Note: Even when switched to the Arabic language, Mobile still uses Latin numbers and Gregorian calendar dates.**
Help and Support: allows you to submit a support request in case of questions or issues related to Mobile. Click the button to submit a support request and get prompt assistance from our team.
Privacy Policy: redirects you to ONCARE's privacy policy page and offers ways to contact ONCARE.
Software Update: provides the ability to check for the latest version of PatientApp available for installation.

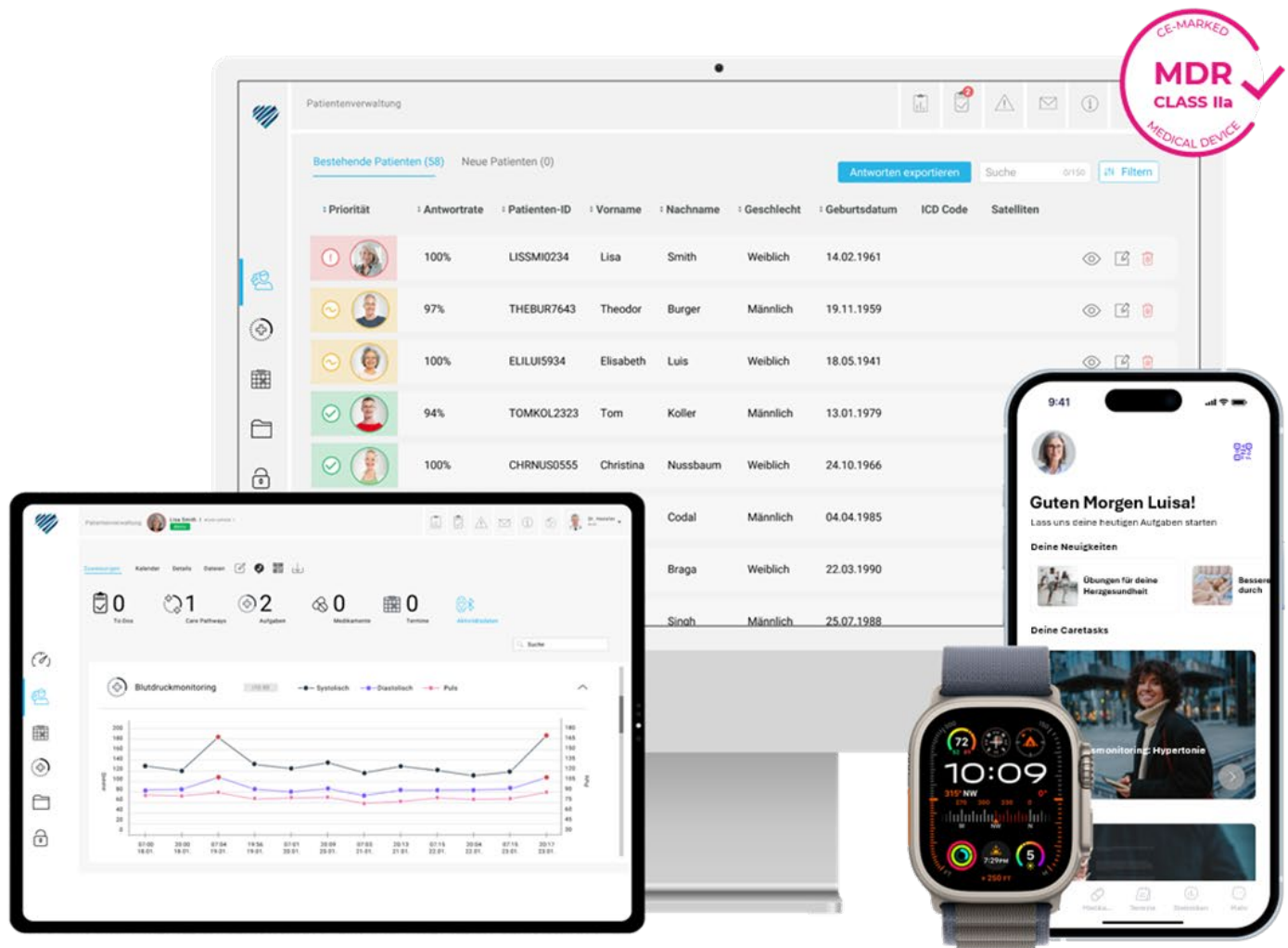| |
|---|
| **Imprint**: includes a short description, information about Mobile (version, LOT and UDI numbers, and manufacturer information). |
| **Email Notification Settings:** allows you to change the email notification settings and toggle them On/Off for both the PatientApp and the PWA. |
| **Activity Data:** allows you to enable and disable the synchronization of your activity data with Apple Health / Google Fit / Withings. To share the data, you need to ensure that Apple Health, Google Fit, or Withings Health Mate are installed on your Smartphone device. As soon as you consent to sharing the activity to PatientApp, you can still manage which data should be synchronized and which should not. **Note: This can be done within the native settings of Apple Health / Google Fit / Withings.**

Note: This functionality is not available for Progressive Web Application.

After consenting to the processing, the synchronization of PatientApp with Apple Health / Google Fit will be initialized when opening the PatientApp. This can lead to small buffering time. |
| **myoncare provides an overview of the consent management screen. You must agree to the Privacy Notice, General Terms and Conditions, and confirm that you are at least 18 years old. Additionally, you can choose to allow or disallow the tracking of your usage data within myoncare application, which helps enhance the user experience.**

Note: please note that revoking the consents will result in the permanent deletion of your account, and this action cannot be undone. |

5. Disclaimer

ONCARE GmbH neither owns nor assumes liability for the content(s) or Caretasks provided to you as these were designed and validated by healthcare professionals and administrators to whom you are connected via scanning a corresponding QR code.

6. Troubleshooting & Reporting

In case you have issues with Mobile and need customer support, please provide us with the following information so we can help you.

- **How would you describe the issue and when did it occur?**
- **Did you receive any push notifications?**
- **Which smartphone and operating system version do you use?**
  Information shall be stated within your device settings)
- **Which version of Mobile is installed?**
  Open Mobile >> profile >> Imprint