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## Health Diagnostics “My Well Record” Software – Instructions for Use (IFU)

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**Purpose:** This Instructions for Use (IFU) document provides users with the information required to safely and effectively use Health Diagnostics’ “My Well Record®” software, in accordance with the UK Medical Devices Regulations 2002 (as amended), which transpose the requirements of the EU Medical Device Directive (93/42/EEC). This IFU includes device identification, intended purpose, operating instructions, warnings, limitations, and incident reporting information. Read this document carefully before use.





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## 1. Device Identification

**Device Name:** My Well Record® (MWR).

	<p>This software is Medical Device Software (SaMD)  <b>Device classification:</b> Class 1 (Rule 12)  <b>UK Responsible Person:</b> Not applicable (UK manufacturer)  <b>UDI-DI:</b> UDI not required for this device class</p>
	<p>UKCA marked medical device in accordance with the UK Medical Devices Regulations 2002 (as amended)  <b>UK Responsible Person:</b> Not applicable (UK manufacturer)  <b>UDI-DI:</b> UDI not required for this device class</p>
	<p>Health Diagnostics Ltd.  Mentor House,  Ainsworth Street,  Blackburn  BB1 6AY</p>
	<p>Important to consult the Instructions for Use prior to operation of this Medical Device</p>

**Regulatory Status:** UKCA-marked medical device, classified as **Class I** (General Medical Device) under the UK Medical Devices Regulations 2002 (UK MDR 2002), which reflects the EU MDD classification. This indicates the software meets applicable essential requirements and has been assessed for safety and performance by the manufacturer. The device has been registered with the MHRA (UK Medicines and Healthcare products Regulatory Agency) as required for all medical devices placed on the Great Britain market. (If the manufacturer were based outside the UK, a UK Responsible Person's name and address would be provided on the product labelling or in this IFU, in accordance with UK regulations. In this case, as a UK-based manufacturer, no separate UK Responsible Person is required.) The UKCA marking and relevant device information can be found on the software's "About" screen or accompanying electronic documentation.

**Software Type:** *Software as a Medical Device (SaMD) – delivered as a Software as a Service (SaaS)*. The software is cloud-hosted on secure servers managed by Health Diagnostics and accessed via a web browser interface. There is no need to install

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special software on local computers; users run *My Well Record* through a standard internet browser over a secure connection Health Diagnostics maintains the backend servers and infrastructure that host the application and patient data.

**Language:** This IFU is provided in English (UK), intended for health professionals and individuals viewing their health check results. In the UK, English is the required language for medical device documentation for healthcare professional use. If this software is supplied in other regions or languages, official translations of the IFU will be provided as necessary.

**Software Version:** As displayed within the application interface

## 2. Intended Use

**Intended Purpose:** My Well Record® is intended to enable healthcare providers to grant individuals secure online access to their personal health results. It presents personalised, easy-to-understand health information and bespoke advice based on the individual's risk profile. The software supports individuals in understanding their health information and making informed health-related decisions. It does not provide a medical diagnosis or replace professional clinical judgement.

### **Intended Users and Use Environment:**

Intended Users:

- Healthcare providers issuing reports
- Individuals accessing their own health information

Use Environment:

- Web-based, non-emergency, community and public-health settings

The software is not intended for emergency use or use by children.

### **Contraindications and Limitations of Use:**

My Well Record® must not be used as the sole basis for clinical decision-making, diagnosis, or treatment. The software is not intended for emergency situations or real-time patient monitoring

### **Warnings and Precautions:**

Warnings:

- Do not rely solely on information presented in My Well Record® for health decisions.
- If you are concerned about your health, seek advice from a qualified healthcare professional.

Precautions:

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- Ensure you access your information in a private and secure environment.
- Keep access links and verification codes confidential.

### 3. Instructions for Operation

#### Healthcare Providers:

1. Complete the relevant assessment or consultation in Interactive Consultations
2. Generate the patient report
3. Issue the report to the individual via My Well Record®.

#### Individuals:

1. Open the attached link received by SMS or email
2. Enter the one time verification code
3. View, download, or print the report as required

### 4. Incident reporting and Vigilance

Any serious incident suspected to be related to My Well Record® must be reported to Health Diagnostics Ltd. and to the relevant national competent authority (e.g. MHRA in the UK), in accordance with local procedures.

### 5. Data Protection

My Well Record® processes personal health information in accordance with applicable data-protection legislation. Users are responsible for safeguarding access credentials and viewing information securely.