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## Health Diagnostics “Self-Assessment” 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’ “Self Assessment” 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:** Self-Assessment(SA).

	<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 Ltd, Suite C1, The Quadrant, Sealand Road, Chester CH1 4QR

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Company Registration 4649183



Diagnostics and accessed via a web browser interface. There is no need to install 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 individual users. 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:** The Self Assessment module is intended to enable adult patients to complete elements of a structured health assessment by providing self reported medical and lifestyle information prior to, or alongside, a clinical interaction.

The software:

- Collects patient reported health and lifestyle data
- Processes responses to identify potential health risks
- Identifies responses that may warrant follow up by a healthcare professional
- Provides individuals with summaries of their responses and signposting to appropriate next steps

The outputs of the Self Assessment module are intended to be reviewed and interpreted by qualified healthcare professionals as part of routine clinical care.

The software does not provide a medical diagnosis, treatment recommendation, or emergency triage, and does not replace professional clinical judgement.

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

Intended Users:

- **Primary users:** Adult patients completing a self assessment about their own health
- **Secondary users:** Healthcare professionals reviewing self assessment outputs as part of clinical workflows

Use Environment:

- Web based environment accessed via a compatible internet connected device
- Nonemergency, community, and public health settings

The Self Assessment module is not intended for use by children, in emergency situations, or by individuals requiring immediate clinical intervention.

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### Contraindications and Limitations of Use:

- The Self Assessment module must not be used for emergency assessment or urgent care
- The software must not be used as the sole basis for diagnosis or treatment decisions
- Responses are based entirely on **self reported information** and may be incomplete or inaccurate
- The software does not continuously monitor health status or provide real time alerts

Failure to observe these limitations may result in delayed or inappropriate care.

### Warnings and Precautions:

#### Warnings:

- **Not a substitute for professional medical advice:** Any information, advice, or signposting provided following a self assessment must not be relied upon as a replacement for consultation with a qualified healthcare professional.
- **User responsibility:** Individuals remain responsible for seeking medical advice if they have health concerns, regardless of self assessment results.
- **No emergency use:** If urgent symptoms are present, individuals should seek immediate medical attention through appropriate services.

#### Precautions:

- Users should answer questions **honestly and accurately**, as incorrect responses may affect outputs.
- Access links, one-time codes, and results should be kept confidential.
- Self assessment results may trigger prompts to book or attend a face to face appointment, which should be followed as advised.

### 3. Instructions for Operation

#### For Individuals (Patients)

1. Access the secure self assessment link provided via SMS or email.
2. Confirm identity and acceptance of terms and privacy information.
3. Complete the on-screen questions as accurately as possible.
4. Review the results summary and any signposted next steps.
5. If advised, arrange follow up with a healthcare professional.

#### Healthcare Providers:

1. Access self assessment results via Interactive Consultations
2. Review patient reported information and identified risk indicators.
3. Interpret results in the context of clinical assessment and professional judgement.
4. Determine appropriate follow up, additional checks, or interventions as required.

#### Residual Risks:

Residual risks associated with Self Assessment include:

- Misinterpretation of results by individuals
- Under-reporting or over-reporting of symptoms
- Delayed presentation to healthcare services

These risks are mitigated through clear warnings, signposting, and clinical review of outputs.

### 4. Incident reporting and Vigilance

Any serious incident suspected to be related to the Self Assessment module 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.

Healthcare professionals should follow local incident reporting procedures. Health Diagnostics operates a post market surveillance and vigilance system to monitor safety and performance and to update the software or IFU where required.

### 5. Data Protection

The Self Assessment module processes personal health information in accordance with applicable data protection legislation.

Individuals are responsible for completing assessments in a private setting and safeguarding access credentials. Health Diagnostics applies appropriate technical and organisational security measures to protect data.