SMARTIBD – Instructions for Use

Software Version 1.0.0

Table of Contents

Odin Vision is a trading name
of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

1. Product Description

1.1. SMARTIBD is an artificial intelligence (AI)/machine learning (ML) based medical device software. SMARTIBD interfaces with the video feed generated by an endoscopic video processor during a colonoscopy procedure.

1.2. SMARTIBD is intended to be used by trained and qualified clinicians as an accompaniment to video endoscopy for the purpose of assisting the assessment of the disease activity for ulcerative colitis based off the mucosal appearance.

1.3. SMARTIBD analyses the data from the endoscopic video processor in real-time and characterizes disease activity in the field of view of the endoscope, in line with the MAYO scoring system for the endoscopic appearance.

1.4. The areas characterized by SMARTIBD are not to be interpreted as definite characterization of ulcerative colitis disease activity. The responsibility to make a decision as to whether or not a highlighted region contains ulcerative colitis, and to what extent lies with the user. The endoscopist is responsible for reviewing suspected areas and confirming the presence or absence of ulcerative colitis, and the degree of disease activity based on their own medical judgment.

2. Indications for Use

2.1. The SMARTIBD system is intended to be used by trained clinicians (users) as an accompaniment to video Endoscopy for the analysis of ulcerative colitis.

2.2. SMARTIBD is trained to process colonoscopy video frames that may contain regions visually consistent with grades of activity of ulcerative colitis.

2.3. SMARTIBD can analyse the visual characteristics and provide information to aid the user to characterize the tissue. This information is interpreted by the user and appropriate actions taken according to the standard clinical practice.

3. Intended Patient Population

3.1. SMARTIBD is intended to be used on any patients over the age of 18 that have been referred for a colonoscopy procedure for the investigation of the colorectal mucosa, whether for screening, surveillance, symptomatic or diagnostic purposes. This does not include pregnant women for which no clinical evaluation has been carried out.

4. Contraindications

4.1. SMARTIBD should not be used when the colonoscopy is operating on a known or suspected perforation of the bowel.

4.2. SMARTIBD should not be used on Pregnant women, for which no clinical evaluation has been completed.

4.3. SMARTIBD should not be used to assess severity, extent or complications of Crohn's disease or diverticular disease.

4.4. SMARTIBD should not be used on patients contraindicated for colonoscopy.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

5. Warnings, Limitations and Precautions

5.1. Only to be used by qualified healthcare professionals for colonoscopy.
5.2. SMARTIBD is a clinical support tool, not to be used as a replacement for clinical judgement or histopathology.
5.3. Avoid overreliance on the device.
5.4. Please ensure that the endoscope is connected through the frame captured card to the client PC.
5.5. Please verify that the endoscope image is displayed after pressing the pedal on the device label page.
5.6. Please verify that the purple image area is defined correctly around the endoscopy image stream. Please contact us if the area needs to be recalibrated.
5.7. Use on a non-compatible endoscopy system could result in unknown performance.
5.8. Inadequate bowel preparation can directly impact the ability of the SMARTIBD system to function as intended.

6. SMARTIBD Setup

6.1. SMARTIBD is accessed via a secure Chromium web browser on a computer that must meets the minimum software and hardware requirements (detailed in section 11).
6.2. The computer takes the endoscopy video feed from the endoscopy image processor. It is connected to the frame captured card on the client (off-the-shelf) computer via an SDI cable.
6.3. The computer is plugged into the video in of the existing main endoscopy monitor observed by the endoscopist.
6.4. It is recommended that SMARTIBD is interacted with using a pedal paired with the space bar. The pedal is connected to the client (off-the-shelf) computer via USB.
6.5. SMARTIBD is logged into with a username and password on a webpage.

7. Notification Symbols

7.1. The notification symbols panel is displayed on the left-hand side of the endoscopy image area, as shown in the highlighted yellow region in the figure below.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

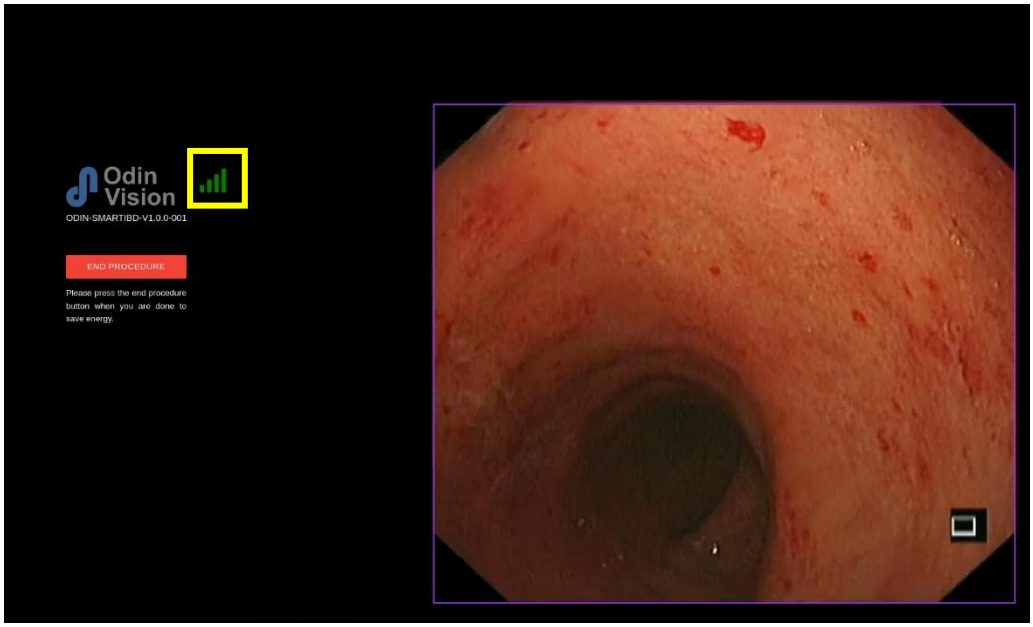

Figure 1: **Notification Symbols.**

7.2. Network Quality

7.2.1. The network quality is represented by a network connection symbol. The colouring and the number of bars represent the quality of the network. The lower the network the connection the higher the latency and delay in the information provided. A strike-through red symbol represents no network connection available. If the network indicator signals no network connection, normal clinical practice should resume, as the SMARTIBD software will not be able to function as intended. Note that these symbols are not an indication of WiFi signal strength.

7.2.2. Note: A wired connection is recommended, as Wi-Fi connections might be less stable.

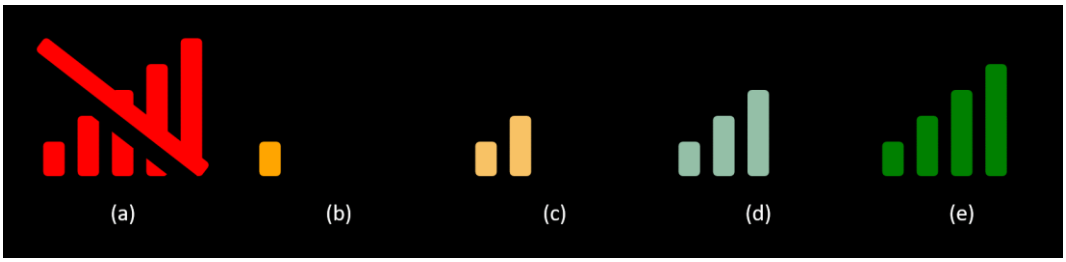

Figure 2: **Network Connection Symbols: (a) > 100 ms and characterisation not responding; (b) > 100 ms; (c) 66 – 100 ms; (d) 33 – 66 ms; (e) < 33 ms.**

7.3. Upload Indicator

7.3.1. Once uploading is complete, the symbol will become a tick, indicating it is finished uploading as seen in figure (a).

7.3.2. Once a procedure is finished and if recording was enabled, the video will begin to upload. Demonstrated by the symbol with an up arrow as seen in figure (b).

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

7.3.3. If a user wishes to see the progress they can hover the mouse and see a percentage. Example at 78% complete as seen in figure (c).

Figure 3: **Upload Indicator**

8. Use

8.1. The device can be accessed through a supported browser (Chromium v83 or higher (for example, Google Chrome or Microsoft Edge)) at the following web address (URL): https://smartibd.odin-vision.com. The login page is illustrated below.

Figure 4: **Login Page**

8.2. The username and password are to be entered. After a successful login, the label page will be displayed as illustrated below.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

Figure 5: **Label Page**

8.3. The “Instructions for use”, can be accessed through a mouse click on the icon in the lower right corner.

8.4. The product’s unique device identifier (UDI), which identifies the specific version of the software for device traceability can be accessed by pressing the i key on the keyboard and is displayed in the lower right-hand corner of the start-up screen next to the instructions for use (booklet) symbol.

8.5. SMARTIBD is started by triggering a switch (this can be done by pressing the foot pedal or a configured key of the keyboard attached to the client computer). The endoscope image stream is displayed with several indicator symbols, which are detailed in Section 7.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

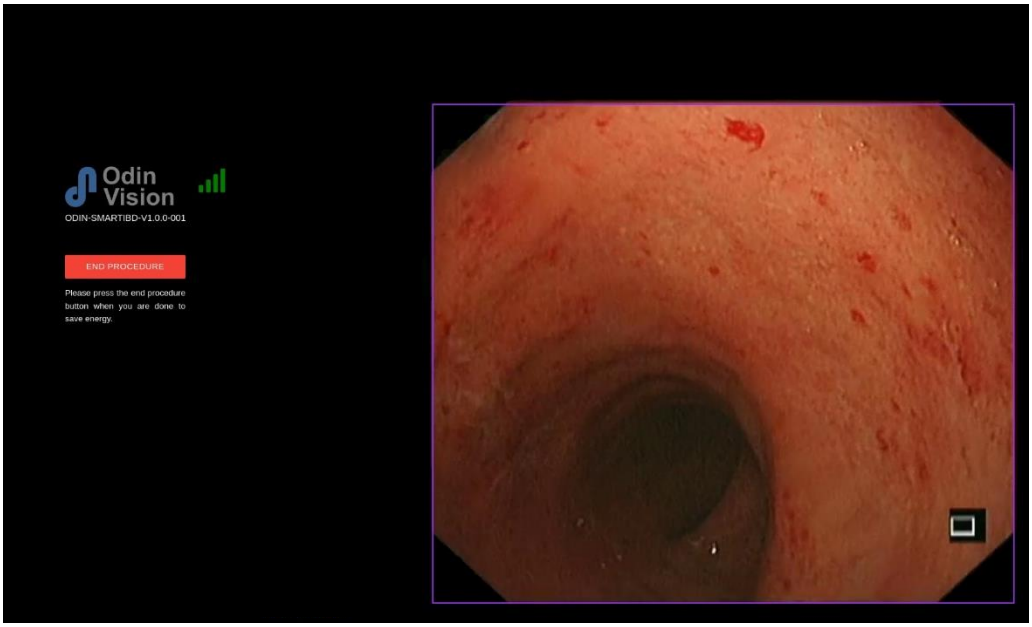

Figure 6: Endoscopic procedure

8.6. Characterisation information for the Ulcerative Colitis MAYO score can be triggered i.e., through a short press of the pedal. The information will be displayed on the screen for 5 seconds. The displayed data can support clinical decisions; however, the device is not designed to be used as a diagnostic tool. The resulting supporting information is displayed at the top of the image area, i.e. MAYO Score: “0”, “1”, “2”, “3” or “Uncertain”.

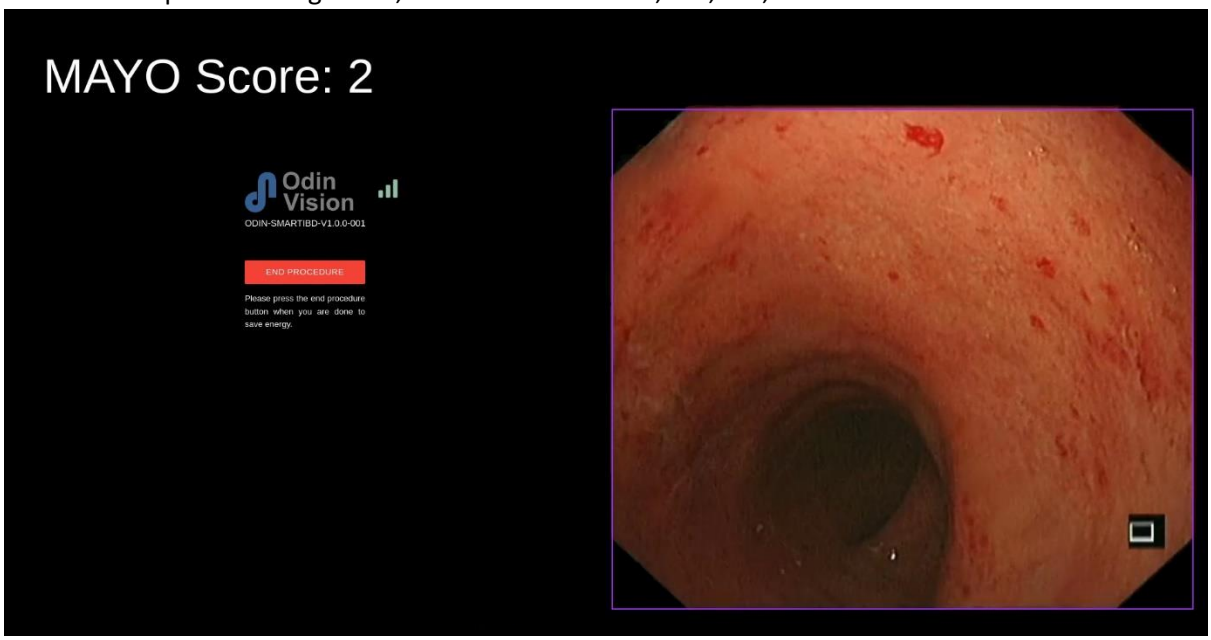

Figure 7: **Characterisation Information displayed**

8.7. If the information displayed is “Uncertain” the camera should be repositioned to centre the tissue and focused before characterization is attempted again.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

8.8. Additional supporting information is presented on the left-hand side of the image area as notification symbols. The notification symbols are detailed in Section 7.

8.9. If configured, video and other data (no patient data) can be recorded during the procedures. The user is notified if data recording is in progress by displaying a camera icon in the status bar of the device, as seen below (highlighted in yellow).

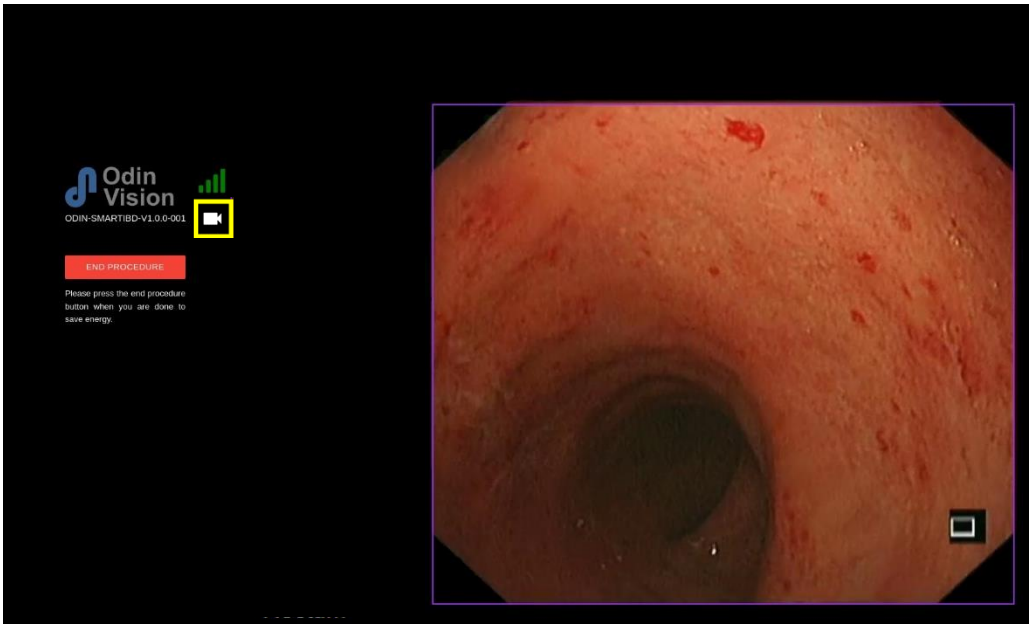

Figure 8: **Recording icon**

9. Interpretation of Results

9.1. Characterisation: The characterization information displayed, when requested, is for decision support only. The information should not be interpreted as a clinical, diagnostic decision. It is solely to support the decision-making process of the user. It should not be used to substitute optical diagnosis or histopathology. (Availability of characterization feature depends on individual user configuration.)

10. Clinical Trial Modes

10.1. Clinical trial modes can be configured for certain users. Such modes can contain additional features to the above. The clinical trial modes cannot be accessed by a user not involved in a clinical trial. If clinical trial mode is configured, the following page is shown after login and before the greeter page (options for modes might vary). The user can cycle and select a clinical trial mode using the pedal. A short press will move the selected mode (larger and lighter box) (Figure 9). Holding down the pedal for 2 seconds then releasing it will select the workflow. A loading box around the selected mode will indicate when the pedal can be released (Figure 10).

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

Figure 9: **Workflow selection**

Figure 10: **Workflow Selected**

10.2. Computer Aided Trial mode will redirect to the SMARTIBD greeter page shown above in section 8.2. Following the on-screen instructions begins the trial procedure with SMARTIBD. Additional trial features might be enabled.

10.3. In all modes for clinical trials it is displayed at all times in the top left corner what mode the user is currently in.

10.4. The upload indicator is available in the top right hand corner

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

11. Minimum Client System Specification

- CPU: Intel i3 (8th gen) or equivalent
- OS: Microsoft Windows 10 or higher
- RAM: 4 GB
- Internet connection bandwidth: 8 Mbit upload, 1 Mbit download. A wired connection is recommended, as Wi-Fi connections might be less stable.
- Chromium Browser (v83 or higher) - for example, Google Chrome
- Frame capture device (providing native resolution and framerate of image processor):
    - Resolution: 720x1280 (HD)
    - Frame rate: 25 Hz
- Monitor (providing native resolution and framerate of image processor):
    - Resolution: 720x1280 (HD)
    - Frame rate: 25 Hz
    - Diagonal screen size at least 26" (inches)
- Audio speakers suitable for the work environment:
    - Integrated into processing PC, or
    - USB compatible, connected to processing PC
- Switch (e.g., foot pedal or keyboard):
    - USB compatible
    - Windows 10 compatible
    - Produces keyboard input that can be paired to the space bar

12. Compatibility with Other Devices

12.1. The software does not interface directly with devices, except for the client computer. The device interacts through the client computer with the frame capture device to receive the endoscopic video feed. The device interacts with a monitor through the client computer, to display information on the monitor.

12.2. SMARTIBD is compatible with endoscopic video processors and scopes that are equipped with standard definition (SD) or higher image quality resolutions. SMARTIBD has not been tested on endoscopy systems with an image quality resolution less than SD. The performance of SMARTIBD may therefore vary if used on endoscopy systems with lower image quality resolutions.

12.3. SMARTIBD is compatible with white light imaging and virtual chromoendoscopy light modalities. SMARTIBD has been tested on Olympus video processors (SD and higher) with white light Imaging. Performance of SMARTIBD using other manufacturers' video processors or virtual chromoendoscopy modalities may vary.

13. Cybersecurity and IT Security Measures

13.1. Users should use a strong password for their SMARTIBD login and protect their login credentials in accordance with their organisations security policies.

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

13.2. Users should use virus protection, firewalls and any other cybersecurity protections (including operating system updates) per local requirements on computers used to access the SMARTIBD software in accordance with their organisations security policies.

13.3. When using computer to access the SMARTIBD software, users should follow their organisations security policies and be cautious of communications that may be phishing or other cybersecurity attacks. User should be cautious of clicking links that claim to be an Odin Vision website or the SMARTIBD software.

13.4. The manufacturer recommends that the client computer is set up on a virtual LAN (VLAN) to isolate all network traffic from other hospital systems.

14. Contact Information

14.1. For questions, information or Customer Support, please contact Odin Medical Ltd. in either of the following ways:

- Email: cs@odin-vision.com
- Online: odin-vision.com

14.2. Any serious incident that has occurred in relation to the device should be reported to the manufacturer (Odin Medical Limited) and the competent authority or regulatory agency of the state in which the user and/or patient is established without delay.

14.3. Any cybersecurity incident that has occurred in relation to the device should be reported to the manufacturer (Odin Medical Limited) without delay.

15. Glossary of Medical Device Symbols

Symbol	Symbol Title	Meaning of Symbol/Description	Standard (or Regulation) Title	Standard (or Regulation) Reference
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.4.3
			Graphical symbols for use on equipment.	ISO 7000-1641
	Manufacturer	Indicates the medical device manufacturer.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.1
			Graphical symbols for use on equipment.	ISO 7000-3082

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

	Medical device	Indicates the item is a medical device.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.7.7
	Country of manufacture	To identify the country of manufacture of products. In the application of this symbol, the "CC" shall be replaced by either the two-letter country code or the three letter country code defined in ISO 3166-1 (Codes for the representation of names of countries and their subdivisions — Part 1: Country codes). The date of manufacture may be added adjacent to this symbol. The date of manufacture may be added adjacent to this symbol.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.1.11
			Graphical symbols for use on equipment.	IEC 60417-6049
	Unique device identifier	Indicates a carrier that contains unique device identified information.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.7.10
	Caution	Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. The symbol variant ISO 7000-0434B ("Caution") may be used.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	ISO 15223-1, clause 5.4.4.
			Graphical symbols for use on equipment.	ISO 7000-0434A

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

UKCA		The UKCA Mark reflects the compliance with UK MDR 2002 requirements. This allows the manufacturer to place their medical device on the UK marketplace.	UK MDR 2002	UK MDR 2002

Odin Vision is a trading name of Odin Medical Limited

Odin Medical Limited
Charles Bell House,
43-45 Foley Street,
Fitzrovia,
London W1W 7TS,
United Kingdom
cs@odin-vision.com

Document: OD-005675-TC

Approved version: 1

Title: ODIN-IBD-IFU Instructions for Use

Approved By:

COO - Luke Sampson	Tue Feb 13 10:50:44 GMT 2024
Approved	`iz3MlWMepC7bOhyzhc75mVL0HaE`

Approval History:

Version	Approved on	Status	Issued by
1	Tue Feb 13 2024	Approved	Beth Hindle
Version	**Approved on**	**Status**	**Issued by**