

# Medtronic

## Endoscopy Operating Unit

Given Imaging Inc.  
15 Hampshire Street  
Mansfield, MA 02048  
USA

[www.medtronic.com](http://www.medtronic.com)

### Request for label exemption for FCC ID: O8PGSB

#### PillCam Genius SB Capsule

Given Imaging Inc. is requesting to place the FCC ID: O8PGSB of the PillCam Genius SB capsule on the package level of the kit which includes the capsule and not directly on the device itself, due to its small size and single use nature.

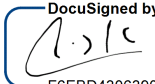
The PillCam Genius SB capsule is part of a PillCam Genius SB Endoscopy kit which includes a Link Device (recorder) as well. The kit supports the capsule endoscopy procedure which enables visualization of the gastrointestinal tract.

The PillCam Genius SB capsule is a single-use ingestible capsule which is designed to acquire images while moving through the patient gastrointestinal tract. The capsule is propelled by natural peristalsis until excreted.

The capsule's physical dimensions are 26.2 mm (length) and 11.4 mm (diameter).

Due to the capsule small size and single use nature, the company therefore intends to have the FCC ID of the capsule listed on the kit labels, as shown in the figures below. The FCC ID will also appear on the insert provided with each kit.

Sincerely,

  
F6EBD4306390484...  
Avishag Metzger

Senior RA manager, Given Imaging

Figure 1. Example of label placed on the primary packaging of the kit

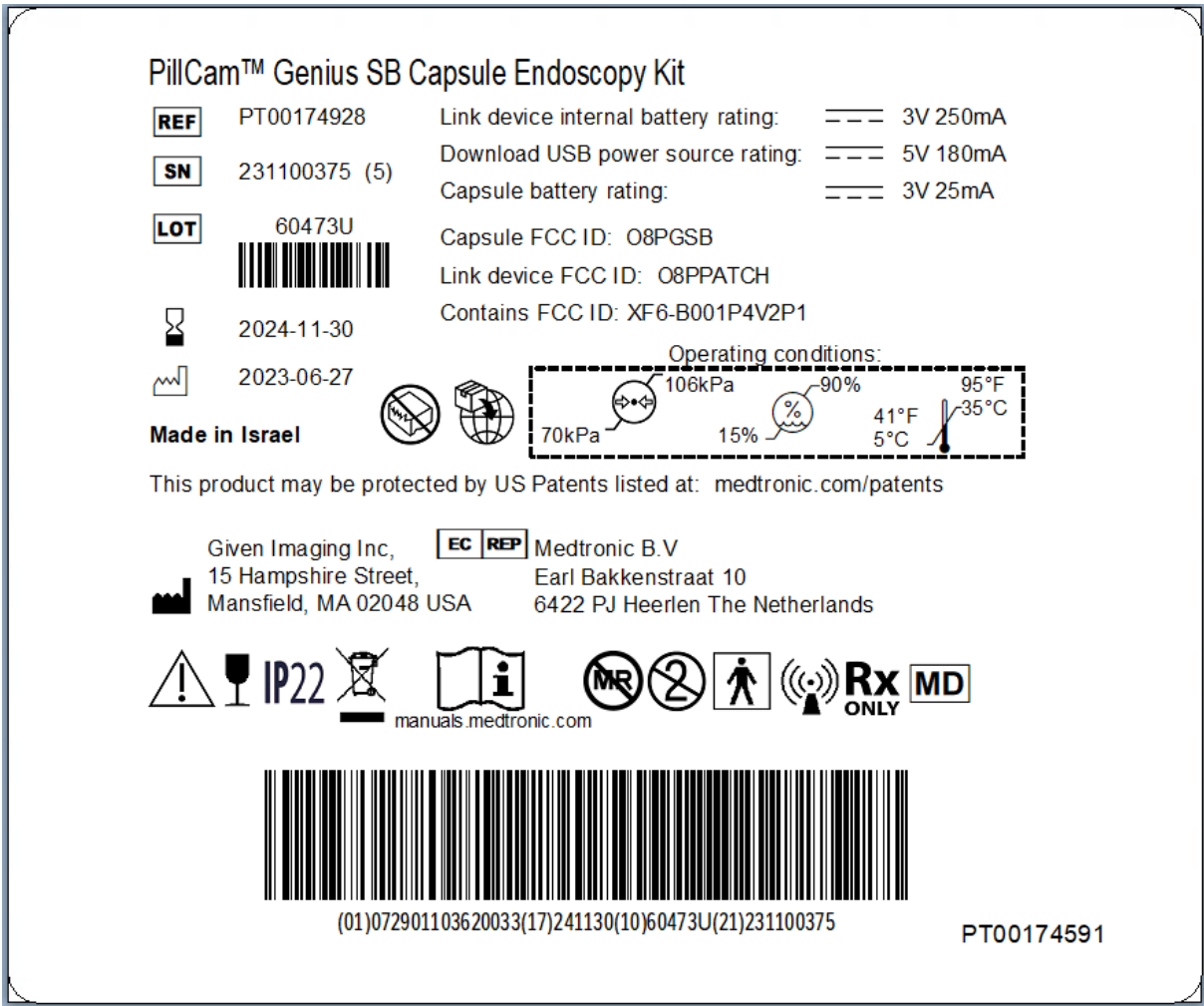





Figure 2. Example of label placed on the secondary packaging of the kit (box)








**PillCam™ Genius SB Capsule Endoscopy Kit**  
**REF** FGS-0574-01  
**LOT** 59692U  **Made in Israel**  
 2023-04-04  
 2023-03-22

Capsule FCC ID: 08PGSB  
Link device FCC ID: 08PPATCH  
Contains FCC ID: XF6-B001P4V2P1  
Link device internal battery rating: --- 3V 250mA  
Download USB power source rating: --- 5V 180mA  
Capsule battery rating: --- 3V 25mA





This product may be protected by US Patents listed at: [medtronic.com/patents](http://medtronic.com/patents)


Given Imaging Inc,  
15 Hampshire Street,  
Mansfield, MA 02048 USA

**EC REP** Medtronic B.V  
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[manuals.medtronic.com](http://manuals.medtronic.com)





**Rx ONLY**

**MD**

  
(01)072901103619900(17)230404(10)59692U

**Link device serial number (SN):**  
230 - 4000 - 293

**Real-Time View password:**  
gedh - vx9 - ueyo

**Encryption key:**  
4ble - hk2j - t623 - 7cj3 - fvv4 - 1cbv - rqwr  
ypuy - zjdq - 4gdt - nfv2 - mp0y - ki



PT00182841  
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