

Medtronic

Endoscopy Operating Unit

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

www.medtronic.com

Request for label exemption for FCC ID: O8PPATCH

PillCam Genius Link Device

Given Imaging Inc. is requesting to place the FCC ID: O8PPATCH of the PillCam Genius Link Device on the package level of the kit which includes the device, and not directly on the device itself, since there is no label on the device and it is intended for single-use.

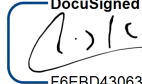
The PillCam Genius Link Device is part of PillCam Genius SB Endoscopy kit which includes a capsule as well. The kit supports the capsule endoscopy procedure which enables visualization of the gastrointestinal tract.

The Genius Link Device is a single-use data recorder that is worn by the patient throughout the PillCam Genius procedure. The device includes an adhesive layer that attaches to the skin of the patient's abdomen. At the end of the procedure, the Link Device is removed and returned to the clinic. After the data is downloaded from the link device it is disposed.

The company therefore intends to have the FCC ID of the Genius Link Device 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,

DocuSigned by:


F6EBD4306390484...
Avishag Metzger

Senior RA manager, Given Imaging

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

PillCam™ Genius SB Capsule Endoscopy Kit

REF


PT00174928

SN


231100375 (5)

LOT

60473U



2024-11-30



2023-06-27

Made in Israel

Link device internal battery rating: --- 3V 250mA

Download USB power source rating: --- 5V 180mA


Capsule battery rating: --- 3V 25mA


Capsule FCC ID: O8PGSB


Link device FCC ID: O8PPATCH

Contains FCC ID: XF6-B001P4V2P1

Operating conditions:

106kPa

90%

95°F

70kPa

15%

41°F

5°C

35°C









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

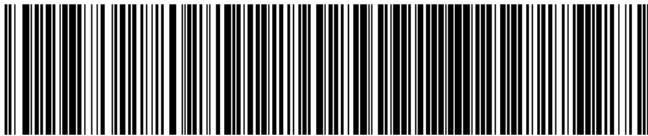
Given Imaging Inc,
15 Hampshire Street,
Mansfield, MA 02048 USA

EC

REP

Medtronic B.V
Earl Bakkenstraat 10
6422 PJ Heerlen The Netherlands

IP22Rx ONLYMD



(01)072901103620033(17)241130(10)60473U(21)231100375

PT00174591

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

PillCam™ Genius SB Capsule Endoscopy Kit


REF

FGS-0574-01


Capsule FCC ID: 08PGSB

LOT

59692U




Made in Israel



2023-04-04

Link device internal battery rating: --- 3V 250mA



2023-03-22

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](https://www.medtronic.com/patents)

Given Imaging Inc,

15 Hampshire Street,








Mansfield, MA 02048 USA




EC REP

Medtronic B.V


Earl Bakkenstraat 10

6422 PJ Heerlen The Netherlands

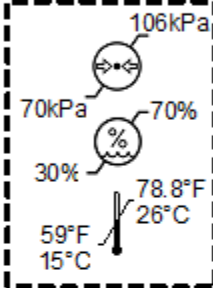
Rx ONLY




MD

manuals.medtronic.com

Storage conditions:





PT00182841

(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