



# Certificate

No. Q5 094769 0012 Rev. 00

**Holder of Certificate:** **Given Imaging, Inc.**  
15 Hampshire Street  
Mansfield MA 02048  
USA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Servicing and Distribution of Devices for the Detection of Pathologies as a tool in the Diagnosis of Gastrointestinal Disorders and for Physiology Visualization such as Pressure, pH, Impedance and Video Capture Systems.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 094769 0012 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_094769_0012_Rev_00)

**Report No.:** 72170681

**Valid from:** 2021-09-07

**Valid until:** 2022-08-23

**Date,** 2021-09-07



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Given Imaging, Inc.  
15 Hampshire Street, Mansfield MA 02048, USA

Management of: Design, Development, Production, Distribution  
and Servicing of Devices for the Detection of Pathologies as a tool  
in the Diagnosis of Gastrointestinal Disorders and for Physiology  
Visualization such as Pressure, pH, Impedance and Video Capture  
Systems.

Given Imaging, Ltd  
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ISRAEL

Design and Development, Production and Distribution of Devices  
for the Detection of Pathologies as a tool in the Diagnosis of  
Gastrointestinal Disorders and for Physiology Visualization such as  
Pressure, pH, Impedance and Video Capture Systems.

GIVEN IMAGING LTD  
7 Hamarpe St, 9777407 Jerusalem, ISRAEL

Production of Devices for the Detection of Pathologies as a tool in  
the Diagnosis of Gastrointestinal Disorders.

Given Imaging Vietnam Co., Ltd.  
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Thuan EPZ, Tan Thuan Dong Ward, District 7, Ho Chi Minh City,  
VIETNAM

Production of Devices for Physiology Visualization such as  
Pressure, pH and Impedance.

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