

Expanding the scope of GI

## EC DECLARATION OF CONFORMITY

We:

**Given Imaging Ltd.**  
**13 Hayetsira St.**  
**New Industrial Zone**  
**Yoqneam 20692, Israel**  
**Tel: 972-4-9097777**  
**Fax: 972-4-9592466**

Declare that the:

**Given<sup>®</sup> Diagnostic System**  
**PillCam<sup>®</sup> SB Capsule**  
**PillCam<sup>®</sup> ESO Capsule**

Meets the provisions of the Council Directive 93/42/EEC concerning medical devices.

Conformity assessment is performed according to Annex II of the Medical Devices Directive.

The standards that were used to prove the product conformity with the essential requirements of the Medical Directive are listed in detail in the Company's QM and in Section 4 of this Technical File.

This conformity is valid from April 1<sup>st</sup> 2001


Shosh Friedman, RAC

Corp. V.P.  
R.A.M.A.

Nov. 8, 2004

**Name**

**Title**

  
**Signature**

**Date**



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This conformity is valid from April 1<sup>st</sup> 2001

Shosh Friedman, RAC  
**Name**

V.P. R.A.M.A.  
**Title**

  
**Signature**

Feb 20/2004  
**Date**



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## DECLARATION OF CLASSIFICATION

According to Annex IX of the Council Directive 93/42/EEC concerning medical devices.

We:  
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Declare that:

**The Product:**  
**Given® Diagnostic System**

**Intended Use:** The Given® Diagnostic System is intended for the detection of pathologies as a tool in the diagnosis of gastrointestinal disorders and diseases.

The system may be used in hospitals, outpatient clinics, and physician offices. After the capsule is swallowed, the patient is not restricted to medical environment

The product is in Class IIa, according to rule 5, in Annex IX of the Medical Directive.

Rami Hazan  
Name

Director of Quality  
Title

  
Signature

Feb 23, 2004  
Date



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**Name and Address of the Manufacturer:**

**Given Imaging Ltd.  
13 Hayetsira St.  
New Industrial Zone  
Yoqneam 20692, Israel  
Tel: 972-4-9097777  
Fax: 972-4-9592466**

**Name and Address of the European Authorized Representative:**

**Manfred Gehrtz,  
Corporate VP, General Manager Europe  
Given Imaging GmbH  
Borsteler Chaussee 47  
22453 Hamburg Germany  
Tel: 49 (40) 51 33 00 33  
Fax: 49 (40) 46 06 96 11**