



Ministry of Health, Welfare and Sport  
CIBG  
P.O. Box 16114  
2500 BC The Hague  
THE NETHERLANDS



Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening  
The undersigned legalises the signature

van/of **M.J. van de Velde**

De minister van Buitenlandse Zaken, voor deze,  
For the minister of Foreign Affairs,

22 feb 2022 - P.C. Swinkels

**STATEMENT**

The undersigned herewith declares that according to the Decree on Medical Devices, which is based on the European Directive 93/42/EEC concerning medical devices,

Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Given Imaging, Inc.  
15 Hampshire Street  
Mansfield, MA 02048  
UNITED STATES OF AMERICA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

**See product list**

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to States and territories outside the European Union. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of VIETNAM .

This statement is valid until August 23, 2022.

The Hague, February 7, 2022

On behalf of the Minister for Health, Welfare and Sport  
Farmatec | CIBG

**Dr. M.J. van de Velde**

Mr. M.J. van de Velde  
Head of Department



Our reference: 20220236  
Certificate number: 34879

NLD603418



**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

1. Quốc gia/ Country: **VIỆT NAM**  
Giấy tờ, tài liệu này / *This public document*
2. do ông/bà **P.C. SWINKELS** ký  
*has been signed by*
3. với chức danh **Viên chức BNG Hà Lan**  
*acting in the capacity of*
4. và con dấu của: **Bộ Ngoại giao Hà Lan**  
*bears the seal/stamp of*  
được chứng nhận/hợp pháp hóa lãnh sự / *certified*
5. tại/và: **The Hague** 6. Ngày/the: **23 / 2 / 2022**
7. Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
8. Số/ No: **297** /2022

**TL. Đại sứ**  
**Bí thư thứ Hai**



  
**Nguyễn Quỳnh Hoa**



Model number	Product name
FGS-4374	Manoscan® A120 Module
4189	Manoscan® Z A200 Module
3920	Manoscan® 3D A300 Module
1286	ManoScan ESO Catheter
800015	ManoScan ESO With Extended Tip
3890	ManoScan ESO Z Catheter
3887	ManoScan ESO Catheter, SD Regular
3886	ManoScan ESO Catheter, SD Small
FGS-8001	ManoScan ESO 3D Catheter
2192	ManoScan AR Catheter, Regular
2195	ManoScan AR Catheter, Small
3885	ManoScan AR 3D Probe
800022	ManoScan ESO Software
FGS-8028	ManoView ESO v3.0.1 Software kit
FGS-8029	ManoView ESO v3.0.1 SW Upgrade kit
FGS-0628	ManoView ESO Software v3.3
800024	ManoScan AR Software
FGS-8030	ManoView AR v3.0 Software kit
FGS-8031	ManoView AR v3.0 Software Upgrade kit
FGS-0571	ManoScan® v3.0 software kit
FGS-0573	ManoScan® v3.0 software kit upgrade
MSE-3462	ManoScan® AR system, portable WS
MSE-3460	ManoScan® ESO system, portable WS
MSE-3460-Z	ManoScan® ESO Z system, portable WS
FGS-8014	PDU, cal chamber mounting kit
150110	PDU, holding plate & top case mount
FGS-8045	ManoScan® WS, Dell 3020 Win 7
FGS-8046	ManoScan® WS, Dell 3020 Win XP GT
FGS-0570	ManoScan® Notebook, Dell E6440 Win 7
FGS-0582	ManoScan® HRM/CLT WS, Dell 3020 W7
3279	Assy, ManoScan Modular Cart
FGS-8039	Assy, ManoScan Cart
3282	Calibration Set Up, Modular Cart
4279	Assy Cart Cal Chamber RigidAR HDMVS
3283	Assy, Modular Cart Accessory Kit
800026	Cal Chamber Mount MVS
800027	Cal Chamber Mount 3DAR
800028	SSI Cal Chamber Mount
800029	Non SSI Cal Chamber Mount 3DAR
4655	Assy Accessory Kit Rigid AR 3DMVS
FGS-0671	GIFD laptop, Win 10 with SW
FGS-0651	GIFD WS PC, 3050 Win 10 with SW
FGS-0684	GIFD WS PC, Win 10 with SW
MSS-3598	Balloon, ARM 150cc, 10-pack
MSS-2599	Balloon, ARM 400cc, 10-pack
MSS-2637	Balloon, ARM 600cc, 10-pack
MSS-2155	Assy, Retail Box of 20, ManoShield EG
MSS-4360	Assy, Retail Box of 20, ManoShield SD
MSS-3599	Assy, Retail Box of 10, ManoShield AR
MSS-4581-3D	Assy, Retail Box of 10, ManoShield 3DAR

  
  
Dr. M.G. van de Velde  
Ministry of Health, Welfare and Sport

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**Manufacturing Facility (ies):**

Given Imaging, Ltd.  
2 Hacarmel St. New Industrial Park  
POB 258, 20692 Yoqneam  
Israel

Given Imaging Vietnam Co., Ltd.  
Suite # 6A, 6th Floor, Standard Factory Building, 14th Street, Tan Thuan EPZ,  
Tan Thuan Dong Ward, District 7, Ho Chi Minh City, Vietnam

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