DECLARATION OF CONFORMITY

1. **Declaration of Conformity date of effectivity:** September 22, 2021

2. **Issuer's Name:** **GIVEN IMAGING, INC.**
   Issuer's Address: 15 Hampshire Street
   Mansfield MA 02048,
   USA

Người đại diện hợp pháp của cơ sở
CÔNG TY TNHH MEDTRONIC VIỆT NAM
Trần Thị Thanh Trà
Trưởng Bộ phận Chất lượng và Pháp chế

Digitally signed by CÔNG TY TNHH MEDTRONIC VIỆT NAM
Date: 2022.03.07 16:55:00 +07'00'

3. **Additional Manufacturing Site:**
   Given Imaging Ltd.
   2 Hacarmel St. New Industrial
   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

4. **Authorized European Representative:**
   Medtronic B.V.
   Earl Bakkenstraat 10,
   6422 PJ Heerlen,
   The Netherlands

5. **Object of the declaration:**
   ManoScan® System

6. **Initial Manufacturing date of the ManoScan System:**
   February 24, 2012

7. **GMDN Code:** 35053
   UMDNS Code: 15036

8. **Device classification: IIa**
   The following Annex IX definition(s) apply to the ManoScan Systems, ManoScan Catheters, ManoScan/View Software, for the purposed of classifications: Per Rule 5, Annex IX, all invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.
   Conformity Assessment Route: Annex II with the exemption of Section 4

9. **The manufacture maintains a Quality System**
   Quality Assurance Certificate: **Q5 094769 0012 Rev. 00 Issue Date: 2021-09-07**

10. **EC Certificate per Annex II,**
    with the exemption of Section 4: **G1 094769 0011 Rev. 00 Issue Date: 2020-11-09**

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ManoScan Modules	
REF	**Description**
FGS-4374	Manoscan® A120 Module
4189	Manoscan® Z A200 Module
3920	Manoscan® 3D A300 Module
ManoScan Catheters	
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
ManoScan, ManoView Software	
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
Portable Workstations	
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
Workstation, cart and related Accessories	
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

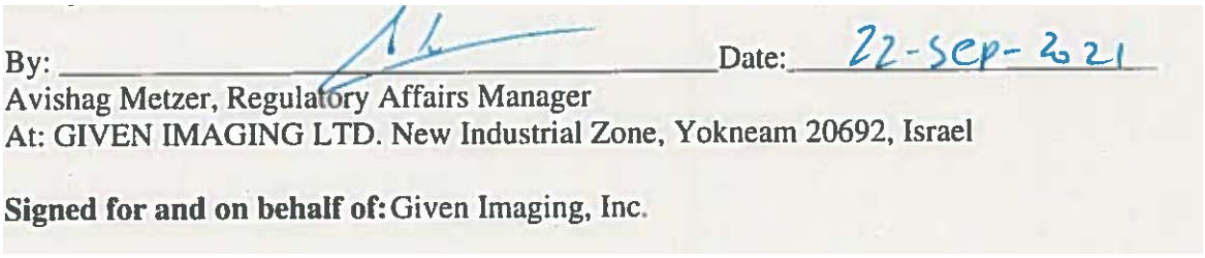
4655	Assy Accessory Kit Rigid AR 3DMVS
FGS-0671	GIFD laptop, Win 10 with SW
FGS-0651	GIFD WS PC, 3050 Win 10 with SW
FGS-0684	GIFD WS PC, Win 10 with SW
Accessories	
MSS-3598	Balloon, ARM 150cc, 10-pack
MSS-2599	Balloon, ARM 400cc, 10-pack
MSS-2637	Balloon, ARM 600cc, 10-pack
MSS-2155	Assy, Retail Box 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

11. Additional Information:

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstraße 65
80339 Munich, Germany
ID 0123

I, the undersigned, hereby declare that the medical devices specified above conform to the applicable Essential Requirements listed in Annex I of EC Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC.

This declaration is supported by an audit of the quality system based upon and assessed according to the provisions in Annex II f the EC-Directive 93/42/EEC, with the exemption of section 4, by TÜV SÜD Product Service GmbH notified body authorized by the German Competent Authority.


By: _____ Date: 22-Sep-2021
Avishag Metzer, Regulatory Affairs Manager
At: GIVEN IMAGING LTD. New Industrial Zone, Yokneam 20692, Israel

Signed for and on behalf of: Given Imaging, Inc.