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Declaration of Conformity

We, Vascular Technology, Incorporated hereby declare under our own responsibility that the following products:

GMDN Term	GMDN Code
Invasive/noninvasive vascular ultrasound probe	62211
Vascular ultrasound system control unit	61236

Meet the provisions of the Council Directive 93/42/EC and the essential requirements which apply to them.

The abovementioned device(s) have been classified as Class IIa devices according to Rules 6 and 10.

This declaration is supported by the Quality Management System certification to ISO 13485:2016 under MDSAP, Certificate No. MD 740977 163587-20 which expires on March 6, 2022 and was issued by TUV Rheinland of North America, Inc., Newtown, CT, USA.

This declaration is based on the conformity assessment of products to the requirements of Annex II, excluding Section 4 according to the EC Conformity Certificate HD 60145551 0001 issued on 2020-01-15, by TUV Rheinland LGA Products GmbH (0197), Tillystrase 2, 90431 Nurnberg Germany which expires on 2024-05-26.

We, Vascular Technology Incorporated, declare under our own responsibility that the listed product(s) in this declaration are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by Vascular Technology Incorporated.

David Regan, VP of Sales

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Annex A – List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

No.	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	Class *	Category**	Rule
1	128160-AC (Mizuho Ref 07-150-20)	20 MHz VTI Microvascular Doppler Transceiver AC Power	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
2	108400	VTI Doppler Transceiver 20 MHz Single Channel	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
3	108400-AC	20 MHz VTI Microvascular Doppler Transceiver AC Power	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
4	108910	VTI Transceiver 8 MHz Selectable Channel Doppler Transceiver	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (8 MHz Frequency)	IIa	1.9	10
5	108910-AC	VTI Transceiver 8 MHz Selectable Channel Doppler Transceiver AC Power	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (8 MHz Frequency)	IIa	1.9	10
6	108720-AC	20 MHz Selectable Depth Doppler Transceiver AC Power	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
7	138200 (Mizuho Ref 07-150-07)	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
8	128160 (Mizuho Ref 07-150-02)	VTI Microvascular 20 MHz Doppler Transceiver	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
9	102802	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6

10	108650	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
11	108380	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
12	108610	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
13	108660	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
14	108670	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
15	108690	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
16	108665	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
17	138660 (Mizuho Ref 07-150-10)	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
18	138210	Disposable Endoscopic Doppler Probe 8 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
19	138665 (Mizuho Ref 07-150-12)	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
20	108370	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
21	108260	Doppler Probe 8 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
22	108200	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
23	128400	20 MHz Doppler Transceiver System	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (20 MHz Frequency)	IIa	1.9	10
24	128770	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
25	108280	Doppler Probe 8 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
26	138220 (Mizuho Ref 07-150-21)	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures.	IIa	1.10	6
27	138230 (Mizuho Ref 07-150-22)	Doppler Probe 20 MHz	Doppler Probe	Surgically Invasive part of the Doppler System. Provides acoustic mapping of arterial blood flow during surgical procedures	IIa	1.10	6

28	108800	8 MHz Trans-Q-Taneous Doppler Transceiver	Doppler System	Provides acoustic mapping of arterial blood flow during surgical procedures (8 MHz Frequency)	IIa	1.9	10
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*The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 (a) & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

** Category:

- 1.1 Sterile medical devices in contact with the patient (e.g. bandages, swabs).
- 1.2 Sterile injecting equipment, infusion, transfusion or drainage as well as probes and catheters and all materials for medical or obstetrical interventions presented as sterile, including irrigation solutions and concentrates for hemodialysis.
- 1.3 Implantable devices (sterile or non-sterile).
- 1.4 Devices for birth control and or prevention of sexually transmitted diseases.
- 1.5 Devices that have a resemblance with medicines and / or have been registered previously.
- 1.6 Devices that are used in dentistry including custom-made devices (eg: amalgam, crowns, dentures), and the necessary systems and consist of such devices.
- 1.7 Systems and kits made-up of devices referred to in 1.1 to 1.5.
- 1.8 Non-invasive and non-sterile medical devices in the form of sterile devices (eg, wadding, bandages, gloves), and the systems and kits that are made-up of these devices.
- 1.9 Active devices (electrical, mechanical or electromagnetic)
- 1.10. Devices with a measuring function
- 1.11. Non-invasive devices, meaning:
 - Body liquid or body tissue collection devices intended to be used in such a way that a return flow is unlikely
 - Devices intended to be used to immobilize body/body parts and/or to apply force or compression on them (for example gravity traction devices, compression hosiery, cervical collars)
 - Devices intended in general for external patient support (for example hospital beds, wheelchairs, devices used for lifting patients)
 - Other devices (intended for a different use) (for examples corrective glasses and frames, stethoscopes, non-invasive electrodes)
- 1.12. Invasive Devices (for examples contact lenses, mirrors) (the MEDDEV refer to mirrors to be used with respect to body orifices, such as handed mirrors used in dentistry to aid dental diagnosis)
- 1.13 Reusable surgically invasive devices
- 1.14 Optical devices, hearing aids, orthopedic devices and the custom-made devices included in these categories
- 1.15 Contact lens solutions

Name of the Manufacturer

Vascular Technology Inc

Name and Position of the Signatory: David J. Regan Vice President of Sales

Date: 05/24/19

Stamp:

