

	EC Declaration of Conformity (DoC)		Page 1 of 1
			DCO#:
	QSP – 040 – 5-3	Revision: B	Effective Date:

EC DECLARATION OF CONFORMITY

1.1 Manufacturer

AccuVein, Inc.

3243 Route 112

Medford, NY 11763

United States of America

1.2 Medical Device

AV500 Vein Visualization System

GTIN 00850019808018

HF580 Wheeled, powered, hands-free Stand

GTIN 00850019808070

HF550 Wheeled, unpowered, hands-free Stand

GTIN 00850019808032

1.3 Classification

Medical Device Class: Class IIa (AV500)

Classification based on 93/42/EEC EU MDD, Annex IX, Rule 10.

Accessory to Medical Device Class: Class I (HF580, HF550)

Classification based on 94/42/EEC EU MDD, Annex VIII, Rule 1.

1.4 Authorized Representative (AR)

Emergo UL Europe

Westervoortsedijk 60

6827 AT Arnhem

The Netherlands

1.5 Notified Body (NB)

British Standards Institute (BSI) (2797)

Say Building

John M. Keynesplein 9

1066 EP Amsterdam

The Netherlands

1.6 Conformity Assessment

Conformity assessment procedure: Annex II, excluding section 4, of the Directive (EU) 93/42/EEC, performed and issued by the British Standards Institute (BSI).

The Medical Device referenced above meets the provisions of Directive (EU) 93/42/EEC on medical devices. BSI Certificate CE 546761, issued 2019-03-08.

This Declaration of Conformity (DoC) is issued under the Sole Responsibility of the Manufacturer, AccuVein, Inc.

Brad Washburne *Brad Washburne March 15, 2024*
Management Representative (MR)
Person Responsible for Regulatory Compliance (PRRC)

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