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)