Section 9 – Declarations of Conformity and Summary Reports

No performance standards or special controls have been developed under Section 514 of the Act for gravity flow infusion system monitors. No special controls apply.

The following list is of the FDA recognized standard for which a Form 3654 is provided following this page.

Declaration of Conformity

As Chief Technology Officer I certify to the best of my knowledge that the Shift Labs DripAssist are compliant to the following:

- IEC 60601-1-2:2007 Ed: 3 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Test

Compliance is demonstrated through an independent evaluation of test data by [redacted]

- There are no deviations from the requirements of these standards.
- There are no substantive differences between the tested devices and production versions.

[redacted] provides third party certification that Shift Labs DripAssist product meets this standard. The address is:

[redacted]

Signature [redacted]