MEDICAL DEVICE VIGILANCE

Please send this form filled in and signed to the email address quality-regulatory@angiodroid.com.

Submitter's details

First name: _____

Last name: _____

Email: _____

Phone: _____

Country: _____

Street: _____

Street number: _____

City name: _____

Postal code: _____

Role: _____

Initial reporter details (only if different from the Submitter)

First name: _____

Last name: _____

Email: _____

Phone: _____

Country: _____

Street: _____

Street number: _____

City name: _____

Postal code: _____

Role: _____

Medical device information

Device code: _____

Device name: _____

Serial number: _____

Device Lot number: _____

Single use accessories code: _____

Single use accessories name: _____

Single use accessories lot number: _____

Single use accessories expiry date: _____

What is the current location of the device?

- ☐ Healthcare facility
- ☐ Distributor
- ☐ Unknown
- ☐ Other: _____

Usage of device:

- ☐ Initial use
- ☐ Reuse of a single use medical device
- ☐ Problem noted prior use: _____

Patient information

Age of patient: _____

Gender:

- ☐ Female
- ☐ Male

List any of the patient's prior health condition, clinical signs, symptom or medication that may be relevant to this incident:

_____
_____

Incident information

Name of healthcare facility where incident occurred: _____

Address of healthcare facility where incident occurred: _____

Date of incident (yyyy-mm-dd): _____

Classification of incident:

- ☐ Serious public health threat
- ☐ Death
- ☐ Unanticipated serious deterioration in state of health
- ☐ Other: _____

Nature of incident (Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)):_____
_____
_____

Remedial actions taken by healthcare facility, patient or user subsequent to the incident: _____
_____
_____

Actual or possible causes/causative factors and conclusions: _____
_____
_____

Identification of similar incidents: _____
_____
_____

Submitter Signature

_____