(103-4) Complaint Report Form

This form is intended to be used to submit complaints to ZuriMED Technologies Inc.
Please send the filled form (including all pages) by email to: complaints@zurimed.com

In case you have any problem submitting your complaint, please contact +1 (919) 342-9833

IMPORTANT NOTE
If you are reporting an event that led, might have led to, or might lead to the death or serious injury* of a patient, user, or other person, please submit this report **on the day the event occurred**. In any other case, please submit the report within **3 business days** after the event occurred (event occurrence = day 0). *Serious injury is an injury or illness that: • Is life-threatening. • Results in permanent impairment of a body function or permanent damage to a body structure, or • Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Reporter Information

Name	
Role, Company	
Email	
Phone	
Complaint filed on behalf of (if applicable)	
Customer Name	
Organization Name	
Address	

Product Information

Product Name	
UDI (Unique Device Identifier)	
SKU / Product Number	
LOT Number	

Complaint Details

Date Issue was observed	
Please describe the issue in detail (e.g. product malfunction, safety concern) *(Attach additional documents if needed)*	
Immediate Action taken by the hospital/surgeon relevant to the care of the patient	
Were there any adverse events associated with the issue? If yes, please describe.	

Did the issue lead to, might it have lead to, or might it lead to the death or serious injury of a patient, user, or other person?	◯ Yes ◯ No
Has the issue been reported to any authority? If yes, provide the name of the authority and any report reference numbers, if available.	

Replacement

Has the device already been replaced? ◯ Yes ◯ No

Do you wish to replace the device? ◯ Yes ◯ No

Return

Is the device available for return? ◯ Yes* ◯ No

Point of contact for return kit delivery	
Address for return kit delivery	

Is the device contaminated? ◯ Yes ◯ No

** Please store the product in an appropriate area while awaiting further instructions.*

_____

Date, Signature Reporter

OFFICE REGISTRATION (For internal use only - Not to be completed by the reporter)	
Date received:	
◯ Feedback (#:)	◯ Complaint (#:)
Justify if no complaint is created	
Received by *(Date, Signature)* **Name** Title	