Incident and Customer Complaint Report Form

Manufacturer: Clouz GmbH, Schinkestr. 9, 12047 Berlin, Germany
SRN: DE-MF-000007330
Notified Body: DQS Medizinprodukte GmbH (NB 0297)

This form is intended for the internal reporting of product complaints or potential incidents related to medical devices. It must be fully completed by the distributor, field representative, or medical device consultant and sent without delay to the manufacturer's vigilance department.

1. Reporting person / Organisation

Name:	
Company / Institution:	
Function / Role:	
Contact (E-mail / Phone):	

2. Product information

Product name:	OneKnot Polyester
UDI-DI:	
Batch / LOT No.:	
Expiry date:	
Quantity affected:	
Sample / return available:	Yes / No

3. Description of the event / complaint

Please describe the event as precisely as possible (date, location, sequence of events, persons involved, observed effects, user reaction, etc.):

4. Impact / consequences

Patient involved:	Yes / No
Health impact:	Yes / No – if yes, please specify:
Immediate actions taken on site:	

5. Preliminary assessment / classification

Type of incident:	☐ Complaint ☐ Incident ☐ Near incident	
Forwarded to manufacturer:	Date:	Recipient:
Received by manufacturer:	Date:	Responsible person:

6. Instructions for use of the form

- This form must be sent to the manufacturer's vigilance department within 24 hours after the event becomes known.
- Please send the completed form by e-mail to: vigilance@clouz.one
- All information is handled confidentially and processed in compliance with GDPR.

Form download: clouz.one/vigilance

Contact: vigilance@clouz.one