Biosite
MEDICAL INSTRUMENTS

# PRODUCT COMPLAINT HANDLING FORM

REGULATORY DEPARTMENT

CUSTOMER CODE:_____

| CUSTOMER INFORMATION | | | |
|---|---|---|---|
| CUSTOMER NAME | | JOB TITLE | |
| HOSPITAL NAME | | HOSPITAL ADDRESS | |
| PHONE NO. | | FAX NO. | |
| EMAIL ADDRESS | | COMPLAINT NO | |

| INCIDENT INFORMATION | | | | | |
|---|---|---|---|---|---|
| DESCRIPTION | PRODUCT CODE | DATE OF INCIDENT | PRODUCT (BATCH & LOT) | EXPIRY | PRODUCT SPECIFICATION/ SIZES |
| | | | | | |
| | | | | | |

PROBLEM DESCRIPTION/ REPORT ATTACHMENT:

TO BE FILLED OUT BY BIOSITE MEDICAL INSTRUMENT

| INITIAL RECOMMENDATION | FINAL RECOMMENDATION | Status of Complaint (check the appropriate parentheses) Please specify whom it was endorsed and action done: |
|---|---|---|
| | | ☐ RESOLVED<br>☐ ENDORSED<br>☐ OTHERS _____<br>REMARKS: |

| ISSUED BY | RECEIVED BY | APPROVED BY |
|---|---|---|
| *(Signature over Printed Name)*<br>DATE SIGNED: | *(Signature over Printed Name)*<br>DATE SIGNED: | *(Signature over Printed Name)*<br>DATE SIGNED: |

BMI-FORM-REG-001

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| PHONE NO. | | FAX NO. | |
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INCIDENT INFORMATION

| DESCRIPTION | PRODUCT CODE | DATE OF INCIDENT | PRODUCT (BATCH & LOT) | EXPIRY | PRODUCT SPECIFICATION/ SIZES |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

NAME OF EVALUATOR:
SIGNATURE:
POSITION TITLE:
DATE OF EVALUATION:

RECEIVED BY:
SIGNATURE:
DATE RECEIVED:
REMARKS:

PROBLEM DESCRIPTION/ REPORT ATTACHMENT:

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| ISSUED BY | RECEIVED BY | APPROVED BY |
|---|---|---|
| *(Signature over Printed Name)*<br>DATE SIGNED: | *(Signature over Printed Name)*<br>DATE SIGNED: | *(Signature over Printed Name)*<br>DATE SIGNED: |

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