INCIDENT REPORT FORM

A. 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)

1.

2.

B. INCIDENT INFORMATION

Number of patients involved:

Operator of device at the time of the incident:

☐ Healthcare professional ☐ Patient

☐ Technician ☐ Other, please specify:

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

C. PATIENT INFORMATION (in case of involvement in the incident)

Date of birth: Patient initials:

Gender:

☐ Female ☐ Male ☐ Unknown ☐ Not applicable

Body weight (kg):

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

EKOM spol. s r.o.
Priemyselná 5031/18
Piešťany 921 01
SLOVAK REPUBLIC

tel.: + 421 33 7967 205
fax: + 421 33 7967 223
e-mail: sales@ekom.sk
www.ekom.sk

INCIDENT REPORT FORM

D. INITIAL REPORTER

Role of initial reporter:

☐ Healthcare professional ☐ Patient ☐ Lay user

☐ Technician ☐ Other, please specify:

Name of healthcare facility where incident occurred:

Healthcare facility report number (if applicable):

Contact's first name: Contact's last name:

E-mail: Phone:

Country:

Street: Street number:

Address complement: PO Box:

City: Postal code:

Was the incident ☐ reported, ☐ notified or ☐ submitted to any medical device database (i.e. MAUDE, EUDAMED etc.)?

Please provide details / reference number:

E. FORM COMPLETED BY

Name: **Company:** **Date:**

Please make sure that "CUSTOMER COMPLAINT FORM" (TQ_P3CCF Form) containing device related information has been submitted to EKOM.

Please send the completed form to: claims@ekom.sk

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