SURICOG

PRODUCT RECALL

Ref. : FSN_20220208_2

Paris, 8 February 2022

Madam, Sir

We hereby inform you that we are conducting a voluntary product recall. Based on our information, we have provided you with the product affected by this recall.

Product affected by this recall:

EyeBrain T2 helmet n°0004-01-1308.

Reason for recall

Repairs to the device concerned have led to the supply of a device that does not comply with the manufacturing specifications, and therefore with the existing regulatory technical file: drilling of an existing plastic box to allow the passage of a cable.

As a result, we are recalling the device concerned

Risks to the patient's health

The proper functioning of the devices was checked after repair, and therefore before sending to customers. There is no risk to the patient's health.

Actions to be taken

1. If you have the product affected by this recall:

- quarantine the product, do not put it into service.

- complete and return the response form (see Annex 1)

- return the product concerned to us.

2. If you no longer own the product concerned:

- complete and return the reply form (see Annex 1).

SWISS MEDIC has been notified of this action.

For any question relating to this recall, please contact Alexandre LEVY by email: alev@suricog.com

SURICOG

We thank in advance for your cooperation, please accept our sincere apologies for the inconvenience caused.

Sincere greetings.

Marc MASSONNEAU

President

Attachment:

- Response Form

SURICOG

PRODUCT RECALL RESPONSE FORM (FSN_20220208_2)

PLEASE SEND THIS FORM BY EMAIL: csel@suricog.com

Establishment / Cabinet	
Address	
Telephone number	
Email	

I, the undersigned (First name, Last name) _____

acting as_____ attests to having received the product recall mail from SURICOG

(Ref. FSN_20220208_2) and :

☐certifies that it does not / no longer disposes of the product concerned by the recall

☐certifies to have the following products, which I return to SURICOG, 130 rue de Lourmel 75015 Paris (France):

Product	Serial number	Quantity
EyeBrain T2 Headset		