Omnidermal

PMCF Customer Report Form

CUSTOMER INFORMATION

Company or Institution Name _____

Address _____

City _____

ZIP Code _____

Country _____

INFORMATION REGARDING THE DEVICE

Device Model _____

Device Serial Number _____

1. Safety Concern regarding Operating Procedures

2. Safety Concern regarding the Equipment Alarms

3. An event has occurred? ☐ **Yes** ☐ **No**

if not please do not fill in this section

EVENT:

- ☐ A malfunction or deterioration in the characteristics of performance
- ☐ Unanticipated adverse reaction or unanticipated side effect
- ☐ Interactions with other substances or products
- ☐ Degradation/destruction of the device (e.g. fire)
- ☐ Inappropriate therapy
- ☐ An inaccuracy in the labelling, instructions for use and/or promotional materials;
- ☐ Other (describe): _____

4. The MANUFACTURER's device is suspected to be a contributory cause of the INCIDENT?

☐ **Yes** ☐ **No**

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5. The event led, or might have led, to:

- Death of a patient, USER or other person: ☐ **Yes** ☐ **No**

- Serious deterioration in state of health of a patient, USER or other person: ☐ **Yes** ☐ **No**

if both answers are no, please do not fill in this section

A serious deterioration in state of health can include (non exhaustive list):

☐ life-threatening illness

☐ permanent impairment of a body function or permanent damage to a body structure

☐ a condition necessitating medical or surgical intervention to prevent a) or b)

☐ any indirect harm as a consequence of an incorrect diagnosis
when the medical device is used within MANUFACTURER´s instructions for use

☐ foetal distress, foetal death or any congenital abnormality or birth defects

☐ Other (describe): _____

_____

_____

6. Deficiency of a device found by the user prior to its use? ☐ **Yes** ☐ **No**

7. Event caused by patient conditions? ☐ **Yes** ☐ **No**

8. Service life or shelf-life of the Medical Device exceeded? ☐ **Yes** ☐ **No**

9. Protection against a fault functioned correctly? ☐ **Yes** ☐ **No**

10. Expected and Foreseeable side effects? ☐ **Yes** ☐ **No**

11. Negligible likelihood of occurrence of death or serious deterioration in state of health?

☐ **Yes** ☐ **No**

Date and Place

_____

Signature of the Person responsible
for the Medical Equipment

_____