



**INTERNAL PRODUCT VIGILANCE
PRELIMINARY REPORT
SCL-MED/ TRM-MED / TRM MED P**

Fax to:
+390296451112

FOR OFFICE USE ONLY:
occurrence.....
receival date.....

GENERAL INFORMATION

Hospital / Customer
Department.....
Contact person name and position.....
.....
Phone..... Fax.....
E-mail:.....
Event date.....
Blanket serial number (see bar code label).....
Transformer serial number (see label stucked on the power cable).....
Supplied by (distributor name).....

DEVICE USE DATA

Estimated number of previous uses.....
Washing cycles (for DM Warm 12 see ticks on the numbered grid attached to the
blanket).....

Separation layer used (cotton, non-woven, etc.).....

The blanket was used : plain folded

Surgical procedure

Length of time of the procedure

The patient temperature was monitored: yes no

If yes, kind of temperature measurement used.....

Age of the patient..... male female

Anti.decubitus devices used during the surgery

Electrosurgery Unit : brand model

Use : monopolar bipolar



When the problem was pointed out

By whom

The product integrity is periodically monitored yes no

If yes, by whom (es.: hosp. Tech. Dept,etc.).....

The device is available for manufacturer's inspection yes no

The user's manual was available to the users yes no

User's manual revision number

Operating table : brand and type.....insulation class :.....

EVENT DESCRIPTION

Please describe what happened, how it happened, what the outcome was, and any other information that could be pertinent. Include photographs and/or drawings if available.

Attach additional pages to this report if necessary.



DESCRIBE ACTION TAKEN – *if any*

COMPILER NAME.....
POSITION

Date:	Fax No.....
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Phone No.....
E-mail.....

Signature.....