

# INITIAL ASSESSMENT FORM – RECALLS AND NON RECALL ACTIONS

24A

RECALLS REFERENCE NUMBER RC-2010-RN-01169-3

PRODUCT name:	thermographic cameras
ARTG Number(s):	143474
Sponsor/Supplier:	
Approval Area:	MEDDEV

PROBLEM Description	requested that the entry of these goods be cancelled from the Australian Register of Therapeutic Goods following a request for information and documents from the TGA.
Product Affected:	Unknown
Distribution of affected product:	8 customers listed

Hazard Category:	Class II
Hazard description:	No clinical evidence
Likelihood*	Likely
Overall Risk*	Moderate
Any related recall actions?	No

Proposed ACTION (supplied product)	Product notification
Level of action	Sponsor
All end users identifiable?	YES – Direct supply by sponsor
Notification method	Mail
End user action(s)	-Read correspondence
Patient follow up?	-NO
Sponsor action(s)	None
Future SUPPLY	-No future supply

Compliance with section 41KA(2)(b)	11(b) Complied. See attached letter (from the manufacturer rather than the sponsor) and the list of 8 customers
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Regulator agreement	Agree with the hazard assessment?	YES / NO
	Agree with proposed action & correspondence?	YES / NO
	Signed: P. Carter Date: 29/11/10	

Comments

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Classification system.

Class I – Class I defects are potentially life-threatening or could cause a serious risk to health.

Class II – Class II defects could cause illness or mistreatment, but are not Class I.

Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

**\*Overall risk table**

	Class III	Class II	Class I
Unlikely	<b>Low</b>	<b>Low</b>	<b>Moderate</b>
Possible	<b>Low</b>	<b>Moderate</b>	<b>High</b>
Likely	<b>Moderate</b>	<b>High</b>	<b>High</b>