

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/40

Issued: 17 May 2007

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section								
<p><b>Medical Device/Equipment:</b> Urine test strips: Makromed – all products with expiry dates in 2007 or 2008.</p>	▶ ①								
<p><b>Problem:</b> Potential for misdiagnosis due to false negative results when testing for blood or ketones in urine.</p>	▶ ②								
<p><b>Action by:</b> Healthcare personnel supplying, using or managing these devices. Staff making clinical decisions based on the results of these devices.</p>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Do not use affected product</li> <li>Identify and quarantine all remaining stock of affected product</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></p> <table> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
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<p><b>Contacts</b> Details of UK distributor, manufacturer and NIAIC contacts for technical aspects</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> None Required</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Makromed urine test strips are manufactured by Makromed Manufacturing (Pty) Ltd, and are distributed in the UK by Sterilab Services.

These urine test strips are intended for the determination of the following parameters: specific gravity, pH, leukocytes, nitrites, protein, glucose, ketones, urobilinogen, bilirubin and blood.

See list of affected batches with expiry dates at Appendix 1.

## 2. PROBLEM:

The manufacturer has received five reports indicating a reduction in sensitivity over time with these test strips. The manufacturer has stated that this problem is caused by a packaging defect with the lid enclosure seal. Through their investigations they have determined that blood and ketone parameters may be affected and, therefore, there is a potential for false negative results.

The UK distributor issued a letter, dated 14 February 2007, recalling all affected product (see letter at Appendix 2). However, the MHRA is issuing this alert in support of the distributor's recall letter, to ensure that all users are aware of this action.

## 3. ACTION BY:

Healthcare personnel supplying, using or managing these devices.  
Staff making clinical decisions based on the results of these devices.

## 4. ACTION:

- Do not use affected product
- Identify and quarantine all remaining stock of affected product

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- All Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Sterile Services Departments
- Laboratories
- Accident & Emergency Departments
- Allied Health Professionals
- Coronary Care
- Intensive Care
- Day Procedure Units

## 6. CONTACTS:

Enquiries to the UK distributor or Manufacturer should be addressed to:

UK distributor:

Manufacturer :

Ken Frizelle  
Sterilab Services  
The Depot  
Morningson Terrace  
Harrogate  
HG1 5DH

Makromed Manufacturing (Pty) Ltd  
15 Lang Street Judith's Paarl 2094,  
Johannesburg,  
South Africa

Tel: 01423 523 300  
Fax: 01423 858 880

Tel : (+2711) 614 8805  
Fax : (+2711) 614 8808

E-mail: [diagnostics.sl@tiscali.co.uk](mailto:diagnostics.sl@tiscali.co.uk)

E-mail: [sales@makro-med.com](mailto:sales@makro-med.com)

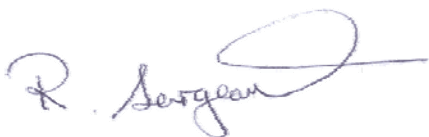
Enquires to NIAIC should quote reference number MDEA(NI)2007/40 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## APPENDIX 1 TO MDEA(NI)2007/40

MAKROMED - RECALLED BATCHES		
Product:	Batch no:	Expiry date
M2T	20774	2007-01
M6	20780	2007-02
M5T	20791	2007-03
M6S	20792	2007-03
M8L	20793	2007-03
M8S	20794	2007-03
M8S	20795	2007-03
M8S(50)	20796	2007-03
M3P	20802	2007-03
M10	20804	2007-04
M10	20805	2007-04
M8L	20806	2007-04
M8L(50)	20807	2007-04
M6S	20808	2007-04
M1	20813	2007-04
M10	20815	2007-04
M 2T	20822	2007-05
M10	20823	2007-05
M8L	20827	2007-05
M6S	20828	2007-05
M8L	20831	2007-05
M6S	20832	2007-05
M5T	20842	2007-06
M8L(50)	20843	2007-07
M6	20844	2007-07
M8L(50)	20848	2007-07
M1K	20850	2007-07
M10	20859	2007-08
M8L	20861	2007-08
M6S	20862	2007-08
M5T	20863	2007-08
M3P	20865	2007-08
M1	20882	2007-09
M6S	20886	2007-09
M8L(50)	20890	2007-09
M8L	20891	2007-09
M5T	20892	2007-09
M2T	20893	2007-09
M10	20894	2007-09
M6	20904	2007-10
M2T	20905	2007-10
M3P	20906	2007-10
M5T	20907	2007-10
M6S	20908	2007-10
M8L(50)	20909	2007-10
M8L	20910	2007-10
M10	20911	2007-10
M8L(50)	20920	2007-11
M8L	20921	2007-11
M5T	20923	2007-11

MAKROMED - RECALLED BATCHES		
Product:	Batch no:	Expiry date
M2T	20774	2007-01
M6	20780	2007-02
M5T	20791	2007-03
M6S	20792	2007-03
M8L	20793	2007-03
M8S	20794	2007-03
M8S	20795	2007-03
M8S(50)	20796	2007-03
M3P	20802	2007-03
M10	20804	2007-04
M10	20805	2007-04
M8L	20806	2007-04
M8L(50)	20807	2007-04
M6S	20808	2007-04
M1	20813	2007-04
M10	20815	2007-04
M 2T	20822	2007-05
M10	20823	2007-05
M8L	20827	2007-05
M6S	20828	2007-05
M8L	20831	2007-05
M6S	20832	2007-05
M5T	20842	2007-06
M6S	20832	2007-05
M5T	20842	2007-06
M8L(50)	20843	2007-07
M6	20844	2007-07
M8L(50)	20848	2007-07
M1K	20850	2007-07
M10	20859	2007-08
M8L	20861	2007-08
M6S	20862	2007-08
M5T	20863	2007-08
M3P	20865	2007-08
M1	20882	2007-09
M6S	20886	2007-09
M8L(50)	20890	2007-09
M8L	20891	2007-09
M5T	20892	2007-09
M2T	20893	2007-09
M10	20894	2007-09
M6	20904	2007-10
M2T	20905	2007-10
M3P	20906	2007-10
M5T	20907	2007-10
M6S	20908	2007-10
M8L(50)	20909	2007-10
M8L	20910	2007-10
M10	20911	2007-10
M8L(50)	20920	2007-11
M8L	20921	2007-11
M5T	20923	2007-11

## APPENDIX 2 TO MDEA(NI)2007/40

### **STERILAB SERVICES**

The Depot, Mornington Terrace  
Harrogate, North Yorkshire  
HG1 5DH  
Tel: 01423 523300  
Fax: 01423 858880

14 February 2007

#### **URGENT IN-VITRO MEDICAL DEVICE RECALL – MAKROMED URINE TEST STRIPS**

Makro Medical (Pty) Ltd has decided to withdraw all models of their Urine Test Strips with expiration dates in 2007 and 2008. This will be all Makromed stocks currently in use.

Our records show you have received Makromed Urine Test Strips.

#### **Reason for recall**

A packaging defect means that the integrity of some units may have been compromised, resulting in a decline in sensitivity over time in blood and ketone parameters of affected units. False negative results have been observed in affected units.

#### **Action requested**

1. Please set aside all open and unopened cans of Makromed product for collection by ourselves in due course.
2. Forward a copy of this notice to each ward/clinic/user who may have received these lots. If you wish, we will undertake this on your behalf.
3. Kindly sign the 2<sup>nd</sup> copy of this advice (attached) to confirm it has been actioned and return in the enclosed pre-paid envelope.
4. We will contact you shortly to arrange to collect product recovered.

Please indicate whether you wish to receive replacement product or credit in full for all remaining cans or part cans.

**Contact:** Your contact person for this Recall is the undersigned.

We confirm that the MHRA is being notified of this Recall.

On behalf of Makromed and ourselves, we apologise for the inconvenience caused and assure you of our full attention. Should you require any further information, please do not hesitate to contact me.

Yours sincerely

**K A FRIZELLE  
PARTNER**

**Direct Phone: 01423 700964  
Fax: 01423 858880**