Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 247 **dated** 29/12/2022 **Regarding NCMDR Recall of ID-DiaPanel from (mfr: DiaMed GmbH).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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سلطنة عُمان
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Circular No. 247 **2022**

05 -06-1444 H

29 -12-2022

Recall of ID-DiaPanel from DiaMed GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&.rid=18374
Product	ID-DiaPanel.
Description	IVD.
Manufacturer	DiaMed GmbH.
Local agent	Bahwan Healthcare Center.
The affected products	ID-DiaPanel (1-11) Catalogue number: 004114 Lot numbers: 769898541 & 45161541 Expiry date: 26/12/2022
Reason	Inability of the IH-500 instrument to read the 2D barcode of the ID-DiaPanel when performing Antibody Identification tests for patients and/or donors on the IH-500 instrument.
Action	1. Refer to "Recall Action Instructions" in the attached recall. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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Australian Government

Department of Health
Therapeutic Goods Administration

Recall Action Notification

ID-DiaPanel (1-11). An in vitro diagnostic medical device (IVD)

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2022-RN-01445-1
Product Name/Description[iii]	ID-DiaPanel (1-11). An in vitro diagnostic medical device (IVD) Catalogue number: 004114 Lot numbers: 769898541 & 45161541 Expiry date: 26/12/2022 ARTG 213161 (Bio-Rad Laboratories Pty Ltd - Reagent red blood cell IVDs)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	24/11/2022
Responsible Entity[vii]	Bio-Rad Laboratories Pty Ltd
Reason / Issue[viii]	Bio-Rad Laboratories has identified an issue regarding inability of the IH-500 instrument to read the 2D barcode of the ID-DiaPanel when performing Antibody Identification tests for patients and/or donors on the IH-500 instrument. This defect results in the following error message for IH-500 users only: "Unreadable reagent barcode". This leads to the impossibility to load the reagent vial using the 2D barcode. Out of the set of 11 vials that constitute the reference 004114, only vial 11 is impacted. This problem does not affect the instrument itself.
Recall Action[ix]	Product Defect Correction

Recall Action Instructions[x]	Bio-Rad are advising customer that under following instructions the product remains usable: 1. The deactivation of the On Board Time function on IH-500. The instrument would use the valid 1D barcode available on the product label. For the details of the procedure (deactivation of On Board Time function on IH-500) please contact your local Bio-Rad techsupport contact. Please note that an advanced or Admin user level could be required. This procedure will lead to the loss of the On Board Time Management information (which defines how long the vial may be used on board), an option to manage the Shelf-Life of the loaded vial. The control of the expiry date of the reagent is not affected. 2. Contact your local technical support to determine the appropriate solution (such as reproducing the 2D barcode). Bio-rad are also advising customers to use the next batch available from November 25th 2022 incase the device is not usable under any conditions describe above
Contact Information[xi]	1800 224 354 - Technical support - Biorad

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification**: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III**- A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action**: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

[x] Recall Action Instructions: What customers with affected goods should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

** These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:
https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf