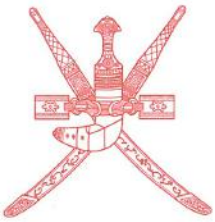
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
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. 196 **dated** 21/10/12 **Regarding NCMDR Field Safety Corrective Action of BOND Enzyme Pretreatment Kits from (mfr: Leica Biosystems).**

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**

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

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سلطنة عمان
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Circular No. 196/ 2020

01 -02-1442 H

21 -10-2020

Field Safety Corrective Action of BOND Enzyme Pretreatment Kits from Leica Biosystems.

Source	National Centre for Medical Devices Reporting- NCMDR. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15377
Product	BOND Enzyme Pretreatment Kits.
Description	IVD Test Reagent/Kits
Manufacturer	Leica Biosystems.
The affected products	Product Code: AR9551 Lot Numbers: All
Reason	Clarification of storage time for Diluted BOND Enzyme, currently may be used up to 30 days at 2-8◦C.
Action	1. Appropriately discard any Diluted BOND Enzyme which is greater than 30 days old. 2. Ensure that any Diluted BOND Enzyme which is less than 30 days old be marked appropriately to have an expiry date which is 30 days from the date of dilution. 3. Contact local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any defect or adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتفنا ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om