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

ننقدم بثقة | رؤية عُمان

**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** 82 **dated** 30/4/2023 **Regarding NCMDR Field Safety Corrective Action of BIOPHEN™ Protein C LRT and BIOPHEN™ Protein C 5 from (mfr: HYPHEN BioMed).**

**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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**Circular No. 82 / 2023**

09 -10-1444 H

30 -04-2023

**Field Safety Corrective Action of BIOPHEN™ Protein C LRT and BIOPHEN™ Protein C 5 from HYPHEN BioMed.**

| | |
|---|---|
| Source | NCMDR - National Center Medical Device Reporting- SFDA.<br>https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19499 |
| Product | BIOPHEN™ Protein C LRT and BIOPHEN™ Protein C 5. |
| Description | IVD. |
| Manufacturer | HYPHEN BioMed. |
| The affected products | BIOPHEN Protein C LRT<br>Reference: 221211<br>Lot: FA07491F, FA18431G, F2001733, FA20041H, FA20461J<br>Basic UDI-DI: 366353700062BB<br><br>BIOPHEN Protein C 5<br>Reference: 221205<br>Lot: FA083327<br>Basic UDI-DI: 366353700063BD |
| Reason | New warnings and precautionary statements on products labelling. |
| Action | 1. Use the new IFU and SDS. Destruct the previous ones.<br>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**

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SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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