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. 28 **dated** 09/02/21 **Regarding NCMDR Recall of ELISIO 17-H, ELISIO 19-H, and ELISIO 19-M from (mfr: Nipro Medical Corporation).**

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

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

Circular No. 28 / 2021

26 -06-1442 H

09 -02-2021

Recall of ELISIO 17-H, ELISIO 19-H, and ELISIO 19-M from Nipro Medical Corporation.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15534
Product	ELISIO 17-H, ELISIO 19-H, and ELISIO 19-M.
Description	Injections / Infusions / Transfusions / Dialysis - dialysis technology.
Manufacturer	Nipro Medical Corporation.
The affected products	Product codes: ELI-17H-GIN, ELI-19H-GIN, and ELI-19M-GIN Lot numbers: see table in the attached FSN
Reason	Blood leakage may occurred during dialysis treatment.
Action	1. All pieces in stock with lot numbers matching the attachment "TO BE RECALLED" list must be shipped back to Nipro Medical Europe. 2. Contact the local agent for remedial action.
Product image	
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

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 - 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

Based on the analysis of the complaint samples received, of retained samples, and of manufacturing records:

LOT TO BE RELEASED:

Product Code	Lot Number
ELI-19M-GIN	20E23K2
ELI-19H-GIN	20E25K2
ELI-19H-GIN	20F09K2
ELI-17H-GIN	20F13K2
ELI-17H-GIN	20F14K2
ELI-17H-GIN	20F16K2
ELI-17H-GIN	20F20K2
ELI-17H-GIN	20F21K2
ELI-17H-GIN	20F29K2

All pieces in stock with lot numbers matching the above-mentioned "TO BE RELEASED" list may be used.

LOT TO BE RECALLED:

Product Code	Lot Number
ELI-19H-GIN	20E27K2
ELI-19H-GIN	20E29K2
ELI-19H-GIN	20F01K2
ELI-19H-GIN	20F05K2
ELI-17H-GIN	20F22K2
ELI-17H-GIN	20G16K2

All pieces in stock with lot numbers matching the above-mentioned "TO BE RECALLED" list must be shipped back to Nipro Medical Europe. Please contact your local Nipro representative for further information about this action.

Transmission of this Field Safety Notice:
This notice should be distributed to the Nurse Manager of each affected facility and to all other persons concerned.

Please act immediately so we are assured that you have received and distributed this important communication. If you have questions regarding this communication, please contact Nipro Medical Europe's Quality department at quality@nipro-europe.com.

Sincerely,

[redacted]

[redacted]

Urgent Field Safety Notice

Release and recall of specific lot numbers of ELISIO™-H and ELISIO™-M dialyzers

NIPRO INDIA CORPORATION (NIC)

- **Product codes**: ELI-17H-GIN, ELI-19H-GIN, and ELI-19M-GIN
- **Lot numbers**: See table below
- **FSCA number**: FSCA 2020/11/12
- **Type of action**: Release and recall of specific lot numbers of ELISIO™-H and ELISIO™-M dialyzers

Dear Sir or Madam,

This communication follows the previous Field Safety Notice communicated to you by Nipro India Corporation, with reference FSCA 2020/11/12, impacting the following products:

- ELISIO™-H dialyzer
- ELISIO™-M dialyzer

Details of the affected devices:

Product Code	Lot Number
ELI-19M-GIN	20E23K2
ELI-19H-GIN	20E25K2
ELI-19H-GIN	20E27K2
ELI-19H-GIN	20E29K2
ELI-19H-GIN	20F01K2
ELI-19H-GIN	20F05K2
ELI-19H-GIN	20F09K2
ELI-17H-GIN	20F13K2
ELI-17H-GIN	20F14K2
ELI-17H-GIN	20F16K2
ELI-17H-GIN	20F20K2
ELI-17H-GIN	20F21K2
ELI-17H-GIN	20F22K2
ELI-17H-GIN	20F29K2
ELI-17H-GIN	20G16K2

[redacted]