

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سُلْطَانَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّعَايَة الْعَامَّة لِلصِّدْقَانِ
وَالرِّقَابَةِ الدَّوْلِيَّةِ
مَسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)
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. 03..... dated 15/11/21 Regarding NCMDR Field Safety Notice of ELISIO 17-H, ELISIO 19-H, and ELISIO 19-M from (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

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سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

Circular No. 03 / 2021

27-05-1442 H

10-01-2021

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

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/ViewRecall.aspx?caid=6&rid=15451
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. Nipro Medical Europe requests that you place all lot numbers of the affected products in quarantine stock until the receipt of further communication from 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL



Urgent Field Safety Notice

Hold stock of ELISIO™ 17-H, ELISIO™ 19-H, and ELISIO™ 19-M

NIPRO INDIA CORPORATION

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

Dear Valued Customers,

We greatly strive for product excellence and would like to provide you with this important update regarding product compliance.

Description of the problem:

Nipro India Corporation received an increasing number of complaints from different countries regarding blood leakage that occurred during dialysis treatment.

As a preventive action, Nipro India Corporation requested Nipro Medical Europe and its customers to hold specific lot numbers of the products affected (ELISIO 17H-GIN, ELISIO 19M-GIN, and ELISIO 19H-GIN) at their respective warehouses until Nipro India Corporation finalizes the complaint investigations.

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

Action to be taken by customers

By virtue of this urgent communication, Nipro Medical Europe requests that you place all lot numbers of the affected products in quarantine stock until the receipt of further communication from Nipro Medical Europe.

Transmission of this Field Safety Notice:

This notice should be distributed to the Nurse Manager of each affected facility and to all other concerned persons. Please complete and return Response letter by 30 November 2020 to Damiano Cani (Complaint and PMS manager) at quality@nipro-europe.com.

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.

We would like to take this opportunity to express our sincere appreciation for your continued business and support.

Sincerely,



Confidential

Field Safety Notice Response Form

NIPRO INDIA CORPORATION

- **FSCA number:** FSCA 2020/11/12
- **Product codes:** ELI-17H-GIN, ELI-19H-GIN, and ELI-19M-GIN
- **Lot numbers:** 20E23K2, 20E25K2, 20E27K2, 20E29K2, 20F01K2, 20F05K2, 20F09K2, 20F13K2, 20F14K2, 20F16K2, 20F20K2, 20F21K2, 20F22K2, 20F29K2, 20G16K2
- **Type of action:** Hold stock of specific lot numbers of ELISIO™-H and ELISIO™ -M dialyzers

Dear Sir or Madam,

Please complete and sign this response form by 30 November 2020.

Hospital name: [Click or tap here to enter text.](#)

Product code and Lot number of products affected: [Click or tap here to enter text.](#)

Contact person name, surname: [Click or tap here to enter text.](#)

Contact person job title: [Click or tap here to enter text.](#)

Contact person email/telephone details: [Click or tap here to enter text.](#)

Response **required**:

- We hereby acknowledge the receipt, distribution, and implementation of this important information. The preventive action has been/will be implemented by our institution.

Please check **one** of the two:

- We have no unit of the products affected by this notice.
- We are affected by this notice of the above lot number(s).

Product code	Lot number	Quantity (units)

Please send this response form by 30 November 2020.

Scan and email this signed form:

To: quality@nipro-europe.com

CC: vanessa.windscheid@nipro-group.com; damiano.cani@nipro-group.com

Date & Location

Signature or stamp of medical center
