Mederen Neotech Ltd.
Address: Harakevet St. 58, Tel Aviv-Jaffa, Israel, postal Code: 6777016
Corporation number: 515505329
www.mederen.com • info@mederen.com

02/01 17.03.2025

Medical Device Safety Notification

Affected device:

CVC Kit Single Lumen Mini S 14G 20 cm: 1. Central venous single lumen catheter 14G 20 cm - 1 pc. 2. Steel guidewire 60 cm - 1 pc. 3. Puncture needle 18G - 1 pc. 4. Dilator 8F - 1 pc. 5. Fixing wings - 1 pc. 6. Injection cap - 1 pc., catalog number MT1MS-14G20, production date 09/18/2022, production date 09/18/2022, lot number 2241301, registration certificate No. RZN 2021/13982 dated 04/12/2021, risk class 3, type code 328850, manufactured by Mederen Neotech Ltd., Harakevet St. 58, Tel Aviv-Jaffa, 6777016, Israel (place of manufacture Ningbo Greatcare Trading Co., Ltd., Address: Unit 93, Building 12, No. 818, Qiming Road, Yinzhou, 315105 Ningbo, Zhejiang, China).

Reason for field safety corrective action:

The company has identified a defect in the production of the medical product CVC Kit Single Lumen Mini S 14G 20 cm, catalog number MT1MS-14G20, production date 09/18/2022, lot number 2241301. No defects in the production of other medical products have been identified. Currently, the reasons that led to the appearance of non-conforming products have been eliminated.

Follow-up actions by Mederen Neotech Ltd:

2,562 packages of products were imported into the territory of the Russian Federation.

Required action for users:

Distributor: Check the availability of the medical product CVC Kit Single Lumen Mini S 14G 20 cm, catalog number MT1MS-14G20, production date 09/18/2022, lot number 2241301 in your warehouses. If such products are available, immediately stop distributing these medical products.

User: Check the availability of the medical product CVC Kit Single Lumen Mini S 14G 20 cm, catalog number MT1MS-14G20, production date 09/18/2022, lot number 2241301 in your warehouses. If such products are available, please:

1) Immediately stop using these medical products;

2) Contact the distributors who supplied you with the medical products to agree on further actions;

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Corrective & Preventive Action Plan:

No	Corrective action steps	Deadline	Status
1	Contact the healthcare organization where the adverse event was reported to establish details of the incident	31.12.2025	Completed
2	Sending a report of the problem to the production site to initiate an on-site investigation	31.12.2025	Completed
3	Blocking of specified medical products in the company's warehouse	31.12.2025	Completed
4	On-site investigation of a medical device	01.03.2025	Completed
5	Corrective actions at the site of manufacture of a medical device	15.03.2025	Completed
6	Informing partners and subjects of circulation of medical devices about the recall of a medical device	01.05.2025	In progress
7	Further actions aimed at resolving the situation	31.12.2025	Not started

We sincerely apologize for any inconvenience caused and hope for your understanding. Patient safety is our company's top priority.

If you have any questions, complaints, or suggestions, please contact our authorized representative in the Russian Federation, Alfamedex LLC, 113 Lakhtinsky Ave., LETTER A, office 2, 197229, Saint Petersburg, Russia; Tel/Fax: +7 (812)-627-21-41; E-mail: info@alfamedex.ru

CEO Natalia Goldberg
Mederen Neotech Ltd.

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