CODAN

CODAN Medizinische Geräte GmbH & Co KG

Telefon +49 (0) 43 63 · 51 11
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www.codan.de

CODAN · Stig Husted-Andersen Straße 11 · D-23738 Lensahn

Important Safety Information

Re-Call of following Products

CODAN I.V.STAR® F 5 Set - 0,9/2,0 mm (ID/OD) (FLL, MLL)	Ref.: 76.3150
CODAN I.V.STAR® F 5 filter (FLL, MLL)	Ref.: 76.3204
CODAN LIGHT-SAFE™ E12 I.V.STAR® F 5	Ref.: 76.3708
CODAN I.V.STAR® F 5 Set - 2,5/4,1 mm (ID/OD)(FLL, MLL)	Ref.: 76.3125

Lensahn, 23 May 2014

Sender: CODAN Medizinische Geräte GmbH & Co KG
Stig-Husted-Andersen Straße 11
D – 23738 Lensahn

Contact Person:

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Addressee: All CODAN Sales Offices, Customers, End-users

Identification of affected Medical Devices:

All CODAN- Product listed above (identification and REF nos). All sets were placed on the market with lipid filters of the manufacturer GVS (product name „Speedflow Kids 1.2- Speedflow Kids HI-FLO 1,2 micron – FLL IN/RMLL OUT").

90.0010.15

Handelsregister: Lübeck HRA 1062 OL
Komplementär: CODAN Dannebrog I/S
Komplementär: CODAN Holding GmbH
Handelsregister: Lübeck HRA 382 OL
Ust-IdNr./VAT NO: DE 135 233 808
Sitz der Gesellschaften: 23738 Lensahn

Sydbank A/S, Flensburg · BLZ 215 106 00 · Konto-Nr. 1 750 410 000
IBAN: DE 292 151 060 017 504 100 00/SWIFT: SYBKDE22

Geschäftsführer:
Deirdre Husted-Andersen, Alexandra Husted-Andersen, Stefanie Husted-Andersen

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Description of Problems including Root Cause:

Because of an actual customer complaint and an official notification to the „Healthcare Products Vigilance Unit" of „INFARMED - National Authority of Medicines and Health Products, I.P., the national surveillance department for medical products in Portugal, CODAN Medizinische Geräte GmbH & Co KG, responsible as per §5 of the German law for medical devices, initiates a product re-call according to §2 section 3 of the "Medizinprodukte- Sicherheitsplanverordnung".

It was complained about that after the infusion was started, cracks occurred in the area of the filter's female Luer Lock which led to a leakage of the infusion solution. The patient suffered from a low blood glucose concentration.

Internal examination proved that the filters from GVS (manufacturer) did not fulfil the requirements regarding stability of their materials used for the housing when used with lipid solutions over the period of the application.

Risks:

- general loss of medication because of leaks (low risk),
- Under-supply because of leak (especially for premature infants (high risk),
- Solution contamination of patients, users and others (non-critical solution, therefore low risk),
- No risks for patients already treated.

Which measures need to be taken by addressee?

All sets specified above need to be collected and securely quarantined. The CODAN representative in charge contacts the customer and organizes the return of the products listed above.

Circulation of information described herein

Within your organisation, please make sure that all users of above mentioned products and all others that need to be informed receive full knowledge of this Urgent Safety Information. If products were handed over to a third party, please pass on a copy of this information or inform the contact person listed below.

Please keep this information at least until these measures are closed. The „Bundesinstitut für Arzneimittel und Medizinprodukte" received a copy of this Urgent Safety Information („Dringende Sicherheitsinformation").

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