Servoprax GmbH
Am Marienbusch 9
46485 Wesel

Urgent safety information
Recall
concerning
Mediware Infusion Set, Ref.- no. H7 0303

11.03.2021

Sender:
Servoprax GmbH
Am Marienbusch 9
46485 Wesel

Adressed to:
Users, Distributors, Risk Managers, Medical device safety officers

Identification of the Medical Devices concerned:

Article Number (Ref.-no.)	**Article description**
H7 0303	Mediware Infusiongerät steril PERFUD.CP-FLEX , mit Belüftung Mediware Infusion Set, sterile
The following batches are affected:	
Batch	**Expiry date**
16F080	31.05.2021
16F081	31.05.2021
17A051	31.12.2021
17K028	31.10.2022
19A065	31.12.2023

As a precaution, please stop using the above products with IMMEDIATE EFFECT.

Description of the problem including the identified cause:

Dear Sir or Madam ,
We would like to inform you with this letter about a precautionary product recall of Mediware Infusion Set, Ref.- no. H7 0303.

We have been informed that significant quality problems have occurred in the sterilization company where the infusion devices were sterilized.
At this point in time, we do not know whether our articles are actually affected by this incident. We have not received any complaints or feedback from our customers regarding this product.
However, to ensure patient safety, we are recalling the above batches as a precaution.
The batches that we currently have in stock were sterilized in another specialised company, do not have any defects and are not affected by this process.

What actions are to be taken by the addressee?

Please carry out the following actions:

- Ensure that this safety information is read and understood by the persons in your organisation who use the above mentioned Infusion Sets.

Servoprax GmbH
Am Marienbusch 9
46485 Wesel

- If you have supplied the product to third parties, please forward a copy of this information to the customers or users concerned.
- Identify the affected batches of the product in your institution/company and ensure that a stock of the products is completely withdrawn from any kind of use. Please destroy any existing batches.

  Please complete the attached customer response form and return it to servoprax GmbH by 26.03.2021.

  If you no longer have any stock of the above products, please also indicate this on the reply form.

Contact person:

If you have any questions or uncertainties in connection with this Safety Notice, please contact the Quality Management Department at the following address

.....(Safety Officer for Medical Devices)

Mail: ..... / Tel. 0281 95283-51.

or to our complaints department, ...

Mail: ..... / Tel. 0281 95283-25

Thank you for your attention and assistance.

Yours sincerely

servoprax

GmbH .....