



MediPac GmbH * Eduard-Rhein-Straße 1-3 * 53639 Königswinter

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 Registergericht: Siegburg HRB 12253
 Geschäftsführer: Dr. h.c. Ferdinand Templin
 Peter Padberg

«Kundenname_vollständig»
 «Straße»
 «PLZ_und_Ort»

 «Land»

20 November 2023

**Urgent safety information:
 Recall of blood collection devices by MediPac GmbH**

Dear Sir or Madam

MediPac GmbH is obliged to withdraw the products of the blood collection devices group from the market due to a regulatory error and to recall products already on the market.

Addressee:

This letter is addressed to all our customers, both retailers and end users such as doctors, blood collection services and hospitals.

Identification of the affected products:

These are the following products, which can be clearly identified by item number and batch number:

Article number new	Article number old	Affected batch numbers	Designation
42301025	42301025H7542000000	32312463	PPS Blutentnahmeggerät - Kanüle 1,5 mm
42301027	42301027H7542000000	32381452; 32474482; 32354412	PPS Blutentnahmeggerät - Kanüle 1,8 mm - Rollklemme
42301031	42301031H7542000000	32131653; 32101562	PPS Blutentnahmeggerät - Kanüle 1,8 mm

Description of the problem including the identified cause:

The affected batches must be recalled for regulatory reasons. The affected products are not authorised as medical devices.

There is no risk for patients, users or third parties when using the products. This corresponds to the assessment by MediPac's quality management and the feedback from the market / users.

What measures are to be taken by the addressee?

Please stop selling the affected products immediately and let us know as soon as possible that you have received this letter and how many of the products you still have in stock. Please check whether your customers have stock of the products and, if so, have them returned to you.

You can send us the number of available blood collection devices informally in a reply e-mail or use the enclosed form. We will collect the affected products from you and refund the corresponding purchase price. Alternatively, you can destroy the affected products and send us an official destruction notification - this must be signed by an authorised signatory from your company, including the name and job title.

Please send us the relevant information no later than 10 working days after sending this letter. The entire measure will be completed by MediPac GmbH by 23 December 2023.

Disclosure of the information described here

Please ensure in your organisation that all users of the above-mentioned products and other persons to be informed are aware of this "Urgent Safety Information". If you have supplied the products to third parties, please forward a copy of this information or inform the contact person specified below.

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

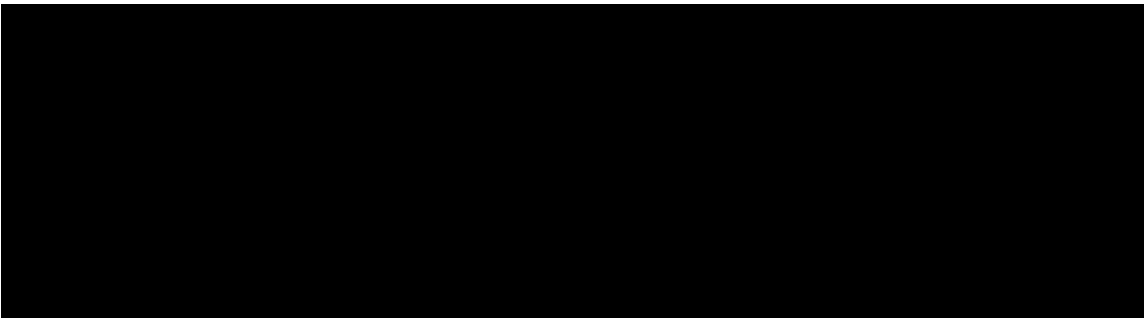
Contact person

If you have any questions about the procedure, please contact the Head of Quality Management at MediPac GmbH, who is also the company's top management representative / responsible person in accordance with Art. 15 MDR. You can reach Mrs Constanze Wagner using the following contact options:

- By post: Eduard-Rhein-Straße 1-3, D-53639 Königswinter, Germany
- By telephone: +49 (0) 2244 927842 - 50
- By e-mail: cwagner@medipac.de

We apologise for any inconvenience caused.

Yours sincerely





Acknowledgement of receipt

Please confirm that the person responsible in your company has taken note of the information below and sent by e-mail today.

Urgent safety information: Recall of blood collection devices by MediPac GmbH

I hereby confirm that I will forward the above information to all customers who have received or used the MediPac GmbH blood collection devices mentioned therein.

Name of your company: _____

Name of contact person: _____

Job title of the contact person: _____

Signature of the contact person: _____

The following number of affected blood collection devices are in stock and must be returned to MediPac GmbH:

Article number new	Batch numbers	Designation	Number of blood collection devices
42301025	32312463	PPS Blutentnahmegesät - Kanüle 1,5 mm	
42301027	32381452; 32474482; 32354412	PPS Blutentnahmegesät - Kanüle 1,8 mm - Rollklemme	
42301031	32131653; 32101562	PPS Blutentnahmegesät - Kanüle 1,8 mm	

- We kindly ask you to collect the affected products
- We will send the products to MediPac
- We will destroy the products and send the destruction protocol to MediPac

Please send this confirmation letter to:

- Mail: Eduard-Rhein-Straße 1-3, D-53639 Königswinter, Deutschland or
- Fax: +49 (0) 2244 927842 – 40 or
- E-Mail: info@medipac.de