



Hippokratec

Gesellschaft für Medizintechnik mbH

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Hippokratec GmbH • Am Windfeld 36 • 83714 Miesbach

Customer Contact Details

Miesbach, 23.07.2015

Urgent safety information silicon tube #1008 kind of note: product recall

Dear Sir or Madam,
we are sorry to tell you, that HIPPOKRATEC GmbH has informed BfArM and other regional authorities about a product recall. Within our quality management we recognized, that we have to recall the silicon tube #1008. We ask for your support in this recall.

Identification of the concerned product

The silicon tube #1008 was delivered as a equipment to the insufflator 1400 and 1800. The pupose of the silicon tube #1008 was to lead co2-gas from the insufflator to a veressneedle or a trokar

Description of the problem

Checking our quality management system we recognized that we do not have a sufficient validation of the sterilization process. We can not be sure, that the user applies a validated sterilization process.

Necessary and urgently measures of the customer

- Please check your stock on silicon tube #1008. Prevent the usage and return every silicon tube #1008 back to HIPPOKRATEC.
- Please fill out the following form, even if there is no silicon tube #1008 in your stock.
- We will provide a substitute as soon as possible.

Pass this security information

Please ensure that all users in your organisation and all other involved persons get informed about this urgent security information. If you gave the silicon tube #1008 to a third person, please hand of a copie of this information or inform HIPPOKRATEC.

Contact

HIPPOKRATEC GmbH
Christian Siedersberger
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Phone +49 8025-28668-0
Email: info@hippokratec.de

A copy of this urgent information was send to Bundesinstitut für Arzneimittel und Medizinprodukte BfArM. We feel sorry for all your trouble and ask for your apology. We thank you for your loyalty and you support.

Yours sincerely

Christian Siedersberger

Reply form für product recall silicon tube #1008

<i>customer</i>	
<i>contact</i>	
<i>adress</i>	

Please enter the number of silicon tube #1008 in the stock of your company

product	stock
silicon tube #1008	

If there is no stock of silicon tube #1008, please enter 0.
Please send us this form in every case with your signiture

Herewith we confirm

- that there is no more silicon tube #1008 in our stock,with the exception of the number in the form.
- That we send all remaining stock back to HIPPOKRATEC

Place, date

signature

Please send your answer to info@hippokratec.de or a fax +49 8025 28668-98 and give the originalform to the return. The adress for the return is

HIPPOKRATEC GmbH
Am Windfeld 36
83714 Miesbach Deutschland