

ECOMEDIS | Gustav-Stresemann-Weg 60 | 48155 Münster

T +49 251 32118-10
F +49 251 32118-09
E info@ecomedis.de
W www.ecomedis.de

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Urgent Security Information

**Dilatator und Schleuse 460 mm lang, d 1,7mm (F5), mit hämostatischem Ventil
REF 31301-2170403 Lot 562035**

Sender:

Ecomedis medizintechnik gmbh
Gustav-Stresemann-Weg 60
48155 Münster
Safety commissioner medical devices: Robert Vogel, M.Sc.

Receiver(s):

All companies, which are distributed or supplied by KPH - Alpha MedTech GmbH, Forellenweg 12/3, A-6392 St. Jakob i.H., who received the medical device

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Identification of affected goods:

Dilatator und Schleuse 460 mm lang, d 1,7mm (F5), mit hämostatischem Ventil REF 31301-2170403 Lot 562035

Description of current problem including determined cause:

For applications in combinations with further medical devices, in which the length of the sluice of the above mentioned product serves as a length measure, special caution is to be observed. The haem. valve is initially pushed onto the dilator when unpacking the product. During use, the valve is connected to the sluice and the dilator is removed. This is resulting in an extension of the length. This extension is to be taken into account when determining the length dimension.

Circulating the above mentioned information:

Please make sure in your organization, that all users and patients will getting all necessary safety information of the above mentioned product. In case that you have given the Refill-Set to a third-party, please sent a copy to your contact person and inform our safety person.

In the end keep all information in safe custody until the file is closed. A copy of this urgent security information is forwarded to The Federal Institute for Drugs and Medical Devices

Contact person:

Robert Vogel, M.Sc., Tel.: +49 251 3211810, Fax +49 251 3211809, Mobil +49 177 8619278

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Medizintechnik gmbh
Gustav-Stresemann-Weg 60
48155 Münster
Tel. 02 51 / 321 18 10, Fax 321 18 09

Robert Vogel
Safety commissioner medical devices