

**By e-mail**

vent-medis GmbH  
**z. Mr. Ilja Hippe**  
Museumstrasse 69

38229 Salzgitter

Hamburg, the 19.12.2019

CK/VM

**IP: 343/19-CK**

*(Please always indicate)*

Translation from the German Original by deepl.com

- **Permitted distribution of graphite crucibles by vent-medis GmbH**
- **Safety message of the company Cyclomedica Germany GmbH on the BfArM website**

Dear Mr. Hippe,

You asked for an opinion on the admissibility of the distribution of the graphite crucibles you put on the market, which are used for the production of Technegas in the Technegas and TechnegasPlus generators of the company Cyclomedica Germany GmbH.

In a letter dated 09.05.2019, the company Cyclomedica Germany GmbH wrote to clinics that use the diagnostic method of pulmonary scintigraphy and to the Federal Institute for Drugs and Medical Devices (BfArM), giving the impression that an incident with the generator was due to the graphite crucible and that the use of the crucible and the provision of services in the operation of the generator by external companies was not permitted. The letter is still available on the BfArM website.

In conclusion, it can be stated that both the services you have provided are lawful, the explanations in this letter are not shared by BfArM and the graphite crucible can be safely used in the generators in question.

In detail:

1. customer service for the Technegas generator:

According to §7 of the Ordinance on the Installation, Operation and Use of Medical Devices (MPBetreibV), a service provider may take over the maintenance of a medical device on behalf of the operator, even without authorisation from the manufacturer, provided he has sufficient knowledge and working materials.

The employees of vent-medis are trained and qualified for this job due to their long-time cooperation with Cyclomedica Germany GmbH. They have done exactly this job for Cyclomedica Germany GmbH for many years.

There is therefore no legal doubt that vent-medis as a service provider for operators of Technegas generators may act as a service provider and that the maintenance does not have to be carried out by the manufacturer himself.

2. reported incident not attributable to "large" graphite crucible/ use of crucible safe

After their comments, the BfArM declared the vigilance proceedings initiated under case number 05693A/19 in response to the notification of the company Cyclomedica Germany GmbH to be terminated with the remark that causation by the graphite crucible cannot be established. This is in line with your own research which comes to the conclusion that a defective valve on an argon cylinder was actually responsible for this.

The letter from Cyclomedica Germany GmbH is still available on the BfArM website. However, this does not mean that BfArM shares the assertions contained therein. BfArM expressly points out that the corresponding website states

**" Note: The customer information available on this page was written by manufacturers, their authorised representatives or importers of medical devices. The specified companies are responsible for the content of the customer information."**

The use of the graphite crucible in all Technegas generators can therefore still be considered safe.

Furthermore, it should also be noted that Cyclomedica Germany GmbH has been using the ('large') graphite crucibles in question in its own generators for a period of more than 10 years. Now claimed safety concerns are therefore obviously advanced and serve only the purpose to unsettle your customers.

3rd summary

The graphite crucible sold by you can be safely used in the TechneGas generators. Even after inspection by the BfArM, there is no danger for patients. The fact that the letter of the company Cyclomedica Germany GmbH is available on the BfArM website does not mean that the BfArM shares the claims made therein.

The services provided by you for operators of the generators are in accordance with the legal regulations, in particular the MPBetreibV, and do not have to be provided by the manufacturer or authorized by the manufacturer.

With kind regards

Christian Karle  
Lawyer