



Emerson Automation Solutions
Tescom Europe GmbH & Co. KG
An der Trave 23-25
23923 Selmsdorf
Germany
T +49-38823-31-0
F +49-38823-31-199

14. Oktober 2019

Important Field Notice

Problem description:

Tescom has identified incorrect information listed in the user's manual for the intended use of the Wegamed series of medical regulators. The intended use indicated in section 2.1 of the user's manual (see below) is not correct for regulators supplied between January 2010 and February 2019. The statement *mobile use, land and air transportation* is not correct. Therefore, use of the regulators in vehicles, including aircraft, is not the intended use of the product as of 2010.

2 PRODUCT DESCRIPTION

2.1 Intended purpose

The pressure regulator is used for a variety of medical equipment in the field of medicine and therapy to regulate the pressure at which medical gases and/or gas mixtures are administered.

- For connection by a trained user to a compressed gas cylinder.
- Only for use with the medical gas and/or gas mixture indicated on the pressure regulator.
- Medical gases and gas mixtures are a medicinal product and may only be administered under the supervision of qualified medical staff who are familiar with the precautions that need to be observed for the respective treatment. The safety data sheets and information provided by the gas manufacturers must be observed.
- For supplying suitable medical equipment in accordance with the technical specifications indicated on the type plate and in the instructions for use.
- For stationary and mobile use, land and air transportation.

Although the product has been certified according to the regulations prior to 2010, Tescom has not continued testing to those requirements since that time, and is not able to follow-up on compliance with the requirements of standards for mobile use. The design and robustness of the product has not changed since then. Our market surveillance has not found any issues with the regulators and therefore there have been no announcements / notices of irregularities as such.

As further background, the associated Declaration of Conformity declares compliance with the Medical Device Directive 93/42/EEC, referring to the harmonized standard DIN EN ISO 10524 (Pressure regulators for use with medical gases). As we do not refer to harmonized standards for



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specific applications (eg. DIN EN 13718), it is important for you, as the customer, to maintain a risk management filing, or similar, by anyone acting as vehicle bodyworker, integrator or user. This filing should consider all risks of integration according the applicable harmonized standard.

Products affected:

This issue is limited **only** to regulators that:

- are coded, starting with:
 - D44244-...
 - D44875-...
 - D50440-...
- supplied between January 1st, 2010 and January 31st, 2019

All other units are not affected by this Notice.

What Tescom is doing:

- Tescom is providing this notice to customers identified as having received affected units and possibly having applications in terms of mobile use, land and air transportation. The units in question are identified by ship date and part number.
- Tescom has revised the user’s manual with an updated intended use. All newly supplied units are provided with updated manual, revision DB. See below.

2 PRODUCT DESCRIPTION	
en	2.1 Intended purpose The pressure regulator is used for a variety of medical equipment in the field of medicine and therapy to regulate the pressure at which medical gases and/or gas mixtures are administered. <ul style="list-style-type: none">• For connection by a trained user to a compressed gas cylinder.• Only for the medical gas or test gas mixture specified on the pressure regulator if the pressure regulator does not have any gas type-specific identifying marking (see Section 5.1).• Medical gases and test gas mixtures are a medicinal product and may only be administered under the supervision of qualified medical staff who are familiar with the precautions for the respective application. The safety data sheets and information provided by the gas manufacturers must be observed.• For supplying suitable medical equipment in accordance with the technical specifications indicated on the type plate and in the instructions for use.• For stationary use in hospitals and clinics.



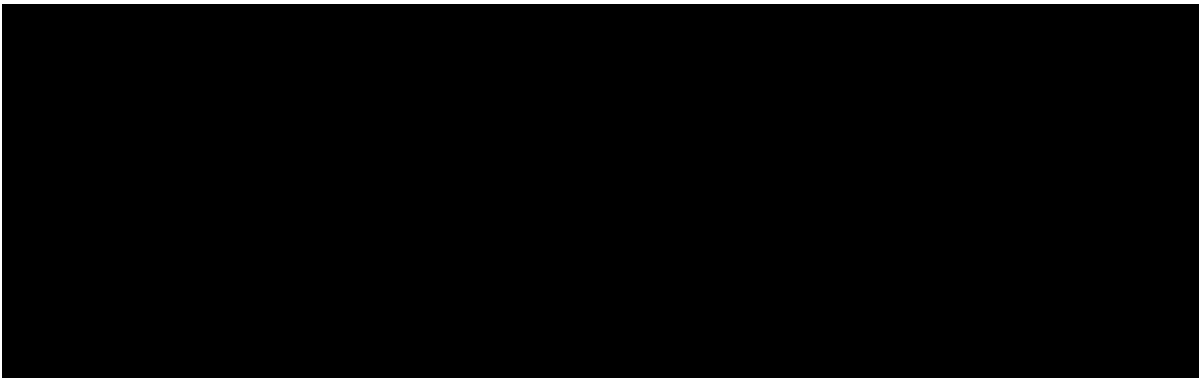
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What you should do:

1. Verify that you have the unit(s) described in the attachment based on the product identification showing the month of manufacturing and determine the status and/or application of the unit(s). For example, has the unit been installed, integrated and placed in service, or is it in inventory pending installation. As needed, convey this verification to your end customers.
2. If the unit is uninstalled, contact Steffen Dunkel (After Sales, phone: +49-38823-31-183) and return the original unit to Tescom at Tescom's expense.
3. If the unit is installed and in service, it should have been integrated by you the customer according to harmonized standard BS EN 13718 (Medical vehicles and their equipment - Air ambulances) or equivalent. Determine whether the application or use leads to residual risks according your risk management filing. If an operational interruption of the regulator is necessary consequently, continue under point 2 (contact us). Please return the original parts to Tescom at Tescom's expense. Consider that Tescom has no alternative product available. If an operational interruption is not necessary, please inform us about this anyway.

If you have any questions, please contact Guido Drissen (phone: +49-38823-31-211) or Christian Manleitner (phone: +49-38823-31-190) at Tescom Europe in Selmsdorf, Germany

Best Regards,





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Table of Potentially Affected Wegamed Regulators

XXX (XX.)

Order Number	# Units	Line Number	Purchase Order	Heat lot code	Serial Numbers
1003320	7	001.1	PC16-256-3*	Z1398	10969364-006 up to -012

