

The System



**Refrigerated  
Box Semitrailer**

**S.KO 24/L – 13.4 FP45**

**Chassis No. WSM0000005208466**

was systematically examined within a  
technical qualification of the compliant type

**Doc. No.: GMP 14-034**

by **Pharmaserv GmbH**

according to the current requirements  
EU-Guideline Good Distribution Practice (GDP),  
Arzneimittel- und Wirkstoffherstellerverordnung (AMWHV)  
(German regulation for manufacturers of medicines and active ingredients)  
as well as the user requirements in the steps  
installation and operational-qualification  
and its suitability  
regarding the transport of temperature sensitive  
pharmaceutical products was confirmed.

The compliance to the qualified type  
was ensured by the manufacturer.

Changes and modifications of the abovementioned system are excluded  
from the qualification certificate and thus also from the qualification.

Marburg, 18 July 2018

  
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Certificate No. Q-0537-14034-0590

[www.pharmaserv.de](http://www.pharmaserv.de)

Zertifikat

## Attachment to the certificate Q-0537-14034-0590

### test object

**Qualification of a compliant type – Schmitz Cargobull S.KO 24/L-13.4 FP45 – carried out by Pharmaserv GmbH according to the qualification plan GMP 14-034 of the March 24th, 2014.**

### scope of testing

- wall thickness 48,5 mm (FP45) and 68,5 mm (FP60)
- single chamber version
- with circulation wall
- without cooling air distributor
- with a tube air chute
- temperature recorder / telematics system with 4 temperature sensors
- cooling unit Schmitz Cargobull T.KM One

### tested temperature range referred to Ph. Eur., USP, WHO\*

- **frozen** <-15°C
- **cold** +2...+8°C
- **ambient** +15...+25°C

### testing environment


**The qualification was done in a test chamber under extreme conditions (worst case).  
- „winter“ < -20°C „summer“ > +30°C**

### validity

**The validity of the qualification depends on the validity of the ATP certificate. Changes and modifications of the abovementioned system are excluded from the qualification certificate and thus also from the qualification.**

- \* Ph.Eur. - Pharmacopoea Europaea  
USP - United States Pharmacopeia  
WHO - World Health Organization

Marburg, 18.07.2018

  
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