



Steinbeis Transferzentrum Tübingen  
Pharmaceuticals - Cosmetics - Medical devices

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# Supplementary Certificate

In regard to the certificate, „GMP – analog manufacturing regarding EG – GMP guideline Annex 15 and PIC/S PI 006-1 requirements“, from 20.3.2005 regarding the product series:

## D-, PUA, PTA45-, K-, und M-

we hereby certify that the below mentioned

**changes in the lifting device**

*meet the requirements concerning the*

*EG – GMP guideline Annex 15 and the PIC/S requirements PI 006-1.*

Manufacturer: Mettler-Toledo (Albstadt) GmbH  
Unter dem Malesfelsen 34  
D - 72458 Albstadt

18<sup>th</sup> June 2007

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## **I. Brief description of the changes in the lifting device**

### **Item 1**

#### **Insertion of a safety catch**

In the “cleaning status” position, the safety catch locks automatically.

Regarding the materials used for the safety catch and –bolt, they consist of stainless steel, types 1.4301 resp.1.4571.

### **Item 2**

#### **Pretension of the lifting device**

The weight which has to be lifted was increased up to 200 kg. Therefore it is necessary to bring the gas strut in a position that allows optimal strength input in the bottom area of the frame. The locating bolt is made of stainless steel type 1.4301. The filling quantity of the gas strut was increased.

### **Item 3**

#### **Stopping levers**

The pre tension of the gas strut is necessary and must be followed by locking the lifting device in the position for weighing. The stopping levers consists of stainless steel, types 1.4301 resp. 1,4571. The cover of the levers consists of polyvinyl chloride with a strength of 80 shore.

The figure one of the following page shows the lifting device in the weighing position. Item 1 to 3 are marked with red circles.

The figure two shows the lifting device in the upwards position. The items 1 to 3 are marked with red circles.



Fig. 1: Lifting device in the position for weighing



Fig. 2: Lifting device in an upwards position



## II. Conclusion

The described changes in the lifting device concern these components:

Item 1: (see fig. 1 and 2) Insertion of a safety catch

Item 2 (see fig. 1 and 2) Change in the position of the gas strut

Item 3 (see fig. 1 and 2) additional insertion of the stopping levers

Regarding the certified balances with the product lines, D-, PUA-, PTA45-, K-, and M, the described changes are minor features. The Cleaning validation and the equipment qualification of the entire product line are unaffected by these changes. The manufacturer attests within his documentation that validity checks had been performed and that there are no effects on the balances and on the process of weighing.

The mechanical components meet the GMP – requirements.

The described changes are implemented and described in detail in the technical description.

Items 1 to 3 don't affect GMP – conform operations (EG-GMP guidelines Annex 15 and PIC/S 006-1 regulations), which are certified on the 1<sup>st</sup> of march 2005.