

ISPE DECLARATION OF CONFORMITY OEB 3

in accordance with the ISPE (formerly the SMEPAC) to establish the particle concentration in room air and particle deposits on surfaces (wipe sampling/swab test).

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Germany

We hereby declare that the machine

Testing system UTS 4.1-S20-TD

has successfully passed the test for mean Human Toxicity Potential OEB Level 3 in accordance with the ISPE, in terms of both its general design and type and the model we have brought onto the market.

The testing system was tested in the following operating states:

- The specimens were fed via the inlet into the device interior. Next, the testing system was parameterized and the specimens were tested under vacuum in the device interior (weight, thickness, diameter and hardness of 66 specimens in 12 minutes).
Results: below 15 µg/m³ or OEB 3
- The specimens were fed via the inlet into the device interior. Next, the testing system was parameterized and the specimens were tested under vacuum in the interior of the device (weight, thickness, diameter and hardness in 5 minutes). This was followed by a power outage.
Results: below 15 µg/m³ or OEB 3
- The specimens were fed via the inlet into the device interior. Next, the testing system was parameterized and the specimens were tested without vacuum in the device interior (weight, thickness, diameter and hardness of 25 specimens in 7 minutes).
Results: below 15 µg/m³ or OEB 3

The three operating states tested were each checked and confirmed by three measurements. Each measurement had a duration of 20-30 minutes.

Authorized agent for technical documentation:

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Darmstadt, November 7, 2019



Thilo Kraemer (CEO)