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CERTIFICATE FOR THE COMMISSIONING INSPECTION OF THE CLEAN ROOMS

FOR THE PURPOSE OF TESTING AND OBSERVATION FOR THE PROOF
OF THE CONTINUING CONFORMITY WITH THE VALID STANDARDS

for the company

**FEG TEXTILTECHNIK FORSCHUNGS- UND
ENTWICKLUNGSGESELLSCHAFT GMBH
PRAGER RING 70
52070 AACHEN**

On November the 17th and 18th, 2014, the commissioning hygienic inspection of the air-conditioning-system and the clean rooms "R18, R19, R23 and R24" at FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH for the operation status "in operation" took place.

The **ISO class 7** (corresponds to the withdrawn US Federal Standard 209 e, class 10,000) for the clean rooms "R19 and R23" with the admissible particle concentrations of 352,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 83,200 particles/m³ for particles $\geq 1 \mu\text{m}$ and 2,930 particles/m³ for particles $\geq 5 \mu\text{m}$ as well as the **ISO class 8** (corresponds to the withdrawn US Federal Standard 209 e, class 100,000) for the clean rooms "R18 and R24" with the admissible particle concentrations of 3,520,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 832,000 particles/m³ for particles $\geq 1 \mu\text{m}$ and 29,300 particles/m³ for particles $\geq 5 \mu\text{m}$ were kept at all measuring points in the clean room under operating conditions during the monitoring time and met the requirements of

DIN EN ISO 14644-1.

The microbiological contamination of the room air in the clean rooms "R19 and R23" did not exceed 100 cfu (= colony forming units) per m³ – with the exception of measuring point 15/3 in "R19" – and corresponded thereby to the request of **GRADE C**.

The microbiological contamination of the room air in the clean rooms "R18 and R24" was below 200 cfu per m³ and corresponded thereby to the request of **GRADE D** of the

EC GMP Guideline.

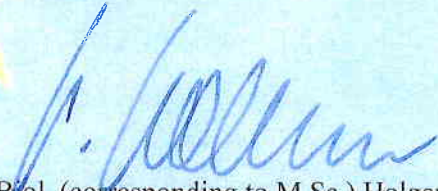
The clean rooms showed differential pressure towards uncontrolled area.

The microbiological investigations of the product-related surfaces documented a high level of the disinfection cleaning technology. The product-relevant values were under the limit value of 25 cfu per contact-plate (with a diameter 55 mm) resp. of 100 cfu per dm² – with the exception of three (3) values – and corresponded to the request of

EC GMP Guideline GRADE C.

Aachen, 28/11/14




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