



Gesellschaft für
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CERTIFICATE

FOR THE ANNUAL HYGIENIC 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 September the 2nd, 2021, the routine hygienic inspection for the re-qualification of the air-conditioning-system and the clean rooms "R18" (changing room), "R19" (chemistry), "R23" (cutting / packaging) and "R24" (washing / drying) at FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH 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The **ISO class 7** (corresponds to the withdrawn US Federal Standard 209 e, class 10,000) for the clean rooms "R19" and "R23" with the admissible particle concentrations of 352,000 particles/m³ for particles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and 2,930 particles/m³ for particles $\geq 5 \mu\text{m}$ as well as the **ISO class 8** (corresponds to the withdrawn US Federal Standard 209 e, class 100,000) for the clean rooms "R18" and "R24" with the admissible particle concentrations of 3,520,000 particles/m³ for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 – 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 in the clean rooms "R19" and "R23" did not exceed the limit value of 25 cfu per contact-plate (with a diameter 55 mm) resp. of 100 cfu per dm² – with the exception of two (2) values – and corresponded to the request of **EC GMP Guideline GRADE C**.

The product-relevant values in the clean rooms "R18" and "R24" were below the limit value of 50 cfu per contact-plate (with a diameter 55 mm) resp. of 200 cfu per dm² – with the exception of one (1) value – and corresponded to the request of **EC GMP Guideline GRADE D**.

Aachen, 17/09/21




Dipl.-Bio. (corresponding to M.Sc.) Holger Stockem
Technical Director