

CERTIFICATE
FOR THE
ANNUAL HYGIENIC INSPECTION

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

for the company

Euro Kunststoff Technik B. V.
De Run 4216
5503 LL Veldhoven

On March the 17th, 2011, the routine hygienic inspection for the re-qualification of the air-conditioning-system of the Arburg-cells 8 and 9 + m. A., the Arburg-box, the flow box 4 "Assembling" and the Fei assembly cell at Euro Kunststoff B. V. took place.

The **ISO class 8** (corresponds to the withdrawn US Federal Standard 209 e, class 100,000) with the admissible particle concentrations of 3,520,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 832,000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 $\geq 5 \mu\text{m}$ was kept at all measuring points in the Arburg-cells 8 and 9 + m. A., the Arburg-box, the flow box 4 "Assembling" and the Fei assembly cell 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 Arburg-cell 9 + m. A. and the Arburg-box was below 100 cfu (= colony forming units) per m³ and corresponded thereby to the request of **GRADE C** of the

EC GMP Guideline.

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 and corresponded to the request of

EC GMP Guideline GRADE C.

The production-hygienic conditions, documented by our measurements, showed comprehensibly that a contamination of the manufacturing goods by the room air of the Arburg-cell 9 + m. A. and the Arburg-box was nearly not possible.

Aachen, 30/03/11



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