

CERTIFICATE FOR 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 April 26th, 2010, the routine control of the air-conditioning-system of the Arburg-cels 8 and 9, the Arburg-box and the flow boxes "Assembling" and "Packaging" at **Euro Kunststoff B. V.** was performed.

The admissible particle concentrations for **ISO class 8** (corresponds to the withdrawn US Federal Standard 209 e, Class 100,000) of 3,520,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 832,000 particles/m³ for particles $\geq 1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 under operating conditions during the monitoring time and met the requirements of

DIN EN ISO 14644-1.

The microbiological contamination of the room air of the Arburg-cels 8 and 9, the Arburg-box and the flow boxes "Assembling" and "Packaging" did not exceed 200 cfu (= colony forming units) per m³ and corresponded thereby to the requirements of

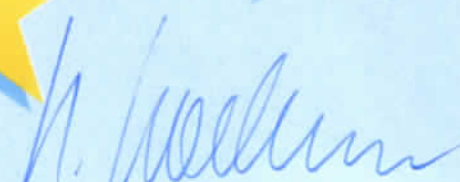
EC GMP- guideline GRADE D.

The microbiological investigations of the product-related surfaces documented a high level of the disinfection cleaning technology. The values were under the limit value of 25 cfu per plate respectively 100 cfu per dm² (according to EC GMP guideline GRADE C).

The production-hygiene conditions, documented by our measurements, showed comprehensibly that a contamination by the room air of the Arburg-cels, the Arburg-box and the flow boxes during manufacturing could be excluded.

Aachen, May 6th, 2010




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