

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 January 8th, 2009, the routine control of the air-conditioning-system of the Arburg-cels 7 and 8, 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The admissible particle concentrations for **ISO Class 8** (corresponding to the withdrawn US Federal Standard 209 e, Class 100,000) of 3,520,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 832,000 particles/m³ for particles $\geq 1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 did not exceed 100 cfu (= colony forming units) per m³ and corresponds thereby to the requirements of

EC GMP- guideline GRADE C.

The microbiological investigations of the product-related surfaces documented a high level of the disinfection cleaning technology. The values were all 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.

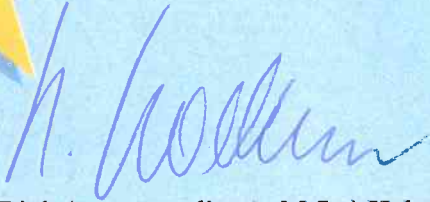
Aachen, January 23rd, 2009



Geschäftsführer: Rüdiger Dietz

Amtsgericht Aachen: HRB 5216

USt.-IdNr.: DE121678680


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

