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# CERTIFICATE

## FOR THE ANNUAL HYGIENIC INSPECTION OF THE CLEAN ROOM

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

for the company

**mecora Medizintechnik GmbH**  
**Rottstraße 35**  
**52068 Aachen**

On March the 29<sup>th</sup>, 2022, the routine hygienic inspection for the re-qualification of the air-conditioning-system and the clean room "clean room 1" at **mecora Medizintechnik GmbH** took place.

The **ISO class 7** (corresponds to the withdrawn US Federal Standard 209 e, class 10,000) with the admissible particle concentrations of 352,000 particles/m<sup>3</sup> for particles  $\geq 0.5 \mu\text{m}$ , 83,200 particles/m<sup>3</sup> for particles  $\geq 1 \mu\text{m}$  and 2,930 particles/m<sup>3</sup> for particles  $\geq 5 \mu\text{m}$  was kept at all measuring points in the clean room 1 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 room 1 did not exceed 100 cfu (= colony forming units) per m<sup>3</sup> and corresponded thereby to the request of **GRADE C** of the **EC GMP Guideline**.

The passive measurements of the microbial contamination of the air in the clean room 1 (measurement of sedimentation for 60 minutes) showed results of less than 50 cfu per plate and corresponded thereby to the request of **GRADE C** of the **EC GMP Guideline**.

The clean room 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 did not exceed the limit value of 25 cfu per contact-plate (with a diameter 55 mm) resp. of 100 cfu per dm<sup>2</sup> 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 clean room was nearly not possible.

Aachen, 13/04/22



  
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