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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 30th, 2022, the routine hygienic inspection for the re-qualification of the air-conditioning-system and the clean room "clean room 2" 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The **ISO class 7** (corresponds to the withdrawn US Federal Standard 209 e, class 10,000) with the admissible particle concentrations of 352,000 particles/m³ for particles $\geq 0.5 \mu\text{m}$, 83,200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 $\geq 5 \mu\text{m}$ was kept at all measuring points in the clean room 2 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 2 did not exceed 100 cfu (= colony forming units) per m³ 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 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 clean room was nearly not possible.

Aachen, 13/04/22




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