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Gesellschaft für
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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

pfm medical CPP S.A.
9, Allee du Quartz
CH 2300 La Chaux-de-Fonds

On April the 15th, 2010, the routine hygienic inspection of the air-conditioning-system and of the clean rooms at **pfm medical CPP S.A.** took place.

For the **clean room 1** (measuring points 1 to 14) the admissible particle concentrations of **ISO class 7** (corresponds to the withdrawn US Federal Standard 209 e, class 10,000) with 352,000 particles/m^3 for particles $\geq$ 0.5 µm, 83,200 particles/m^3 for particles $\geq$ 1 µm and 2,930 particles/m^3 for particles $\geq$ 5 µm as well as
for the **NIVAROX room** (measuring points 15 to 20) the admissible particle concentrations of **ISO class 6** (corresponds to the withdrawn US Federal Standard 209 e, class 1,000) with 35,200 particles/m^3 for particles $\geq$ 0.5 µm, 8,320 particles/m^3 for particles $\geq$ 1 µm and 293 particles/m^3 for particles $\geq$ 5 µm
and for the **laminar flow cabinet** (measuring point 21) the admissible particle concentrations of **ISO class 5** (corresponds to the withdrawn US Federal Standard 209 e, class 100) with 3,520 particles/m^3 for particles $\geq$ 0.5 µm, 832 particles/m^3 for particles $\geq$ 1 µm and 29 particles/m^3 for particles $\geq$ 5 µm were kept at all measuring points under operating conditions during the monitoring time and met the requirements of

ISO 14644-1.

The microbiological contamination of the room air in the clean room 1 and the NIVAROX room did not exceed 100 cfu (= colony forming units) per m^3 (with the exception of the measuring point 8/3 in the clean room and 20/1 in the NIVAROX room) and corresponded thereby to the request of

EC GMP- guideline GRADE C.

The clean rooms showed significant 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 – with two exceptions - were under the limit value of 100 cfu per dm^2 (according to EC GMP-Guideline GRADE C).

The production conditions, documented by our measurements, showed that a contamination of the manufacturing goods by particles caused by the air conditioning system during the operation time was nearly not possible.

Aachen, April 30th, 2010

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Stamp

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