

# Certificate

Nr.: TR-700456-10032020-E

For the (re-) qualification examination of cleanrooms the conformity regarding the requirements of DIN EN ISO 14644:2015

## Company:

Nanogate Medical Systems GmbH, Osemundstr. 27-29, 58566 Kierspe

Examination date:	10.-11.03.2020
Validity Certificate:	11.03.2021
ISO-class:	7, 8
GMP grade:	C, D
Test location:	Nanogate Medical Systems GmbH Osemundstr. 27-29 58566 Kierspe
Operation status:	in operation

## DIN EN ISO 14644:2015

The requirements of DIN EN ISO 14644:2015 for permissible particle concentrations of the room air in the cleanliness ISO class 7, 8 were kept faultless at all measuring points under operation status in operation. The clean rooms and clean room areas had differential pressure or directed displacement air flow to the non controlled areas.

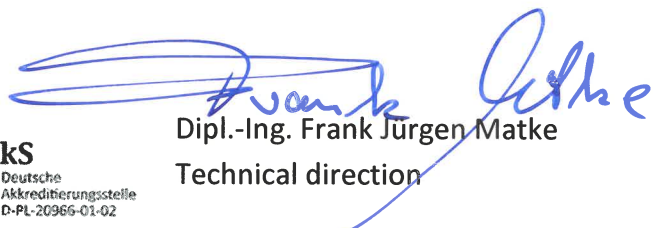
## EU GMP

The microbiological contamination of the room air and the microbiological contamination of the surfaces in the clean rooms and clean rooms areas were fulfilled faultless at all measuring points the requirements of the EU GMP Guideline Grade C, D .

Deviations accordings to the following report

Reutlingen, the 19.03.2020

M.Sc. Isabel Matsch  
Laboratory managment



Dipl.-Ing. Frank Jürgen Matke  
Technical direction