

Certificate

mdc medical device certification GmbH
certifies that

Mikrogen GmbH
Anna-Sigmund-Str. 10
82061 Neuried
Germany

for the scope

**Development, production and distribution of in vitro diagnostics for
cell-based determination of the immune status, serological and molecular
diagnosis of viral and bacterial infections and other diseases;
Installation and servicing of analysers;
Production and distribution of raw material for the diagnostic industry**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-11-16
Valid until	2026-11-15
Registration no.	D1060500057
Report no.	P23-00485-272098
Stuttgart	2023-10-12


Head of Certification Body

