

June 19, 2024, Statement of the management:

In May 2024 emka MEDICAL was audited by MedCert, the company's Notified Body, about its ISO13485 certification. A few minor deviations were detected.

emka MEDICAL implemented the necessary corrections and forwarded documents to MedCert.

MedCert has confirmed that the corrections are satisfactory and we now expect that ISO13485 certification will be expanded for 3 years, until May 2027. The renewed certificate will replace the present certificate that expired 1 month ago, on May 25, 2024 (shown below).



Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

emka Medical GmbH
Erthalstraße 12
63739 Aschaffenburg
Germany

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection and distribution of

- Pressure transducers
- Sensors for oxygen, temperature and lactate
- Data loggers for recording of physiological parameters
- Software for displaying physiological parameters

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-05-25
Expiry date: 2024-05-21

Report No.: 7049FS12F
Procedure No.: QS – 7049
Certificate No.: 7049GB445210525A

Hamburg, 2021-05-25

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAkkS accredited management systems
certification body

