

Certificate

mdc medical device certification GmbH
certifies that

Dr. Fenyves und Gut Deutschland GmbH
Daimlerstraße 23
72414 Rangendingen
Germany

for the scope

**design, manufacturing, final inspection and distribution of
PC-Software and devices for sleep diagnosis**

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	2023-12-18
Valid until	2026-12-17
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Head of Certification Body

