

# Certificate

We hereby certify the company

**bioactiva diagnostica GmbH**  
**Louisenstraße 137**  
**61348 Bad Homburg**  
**Germany**

**bioactiva diagnostica**  
*The Partner That Cares*



the introduction and application of a

## **Quality management system according to EN ISO 13485**

in the scope

development, manufacturing and distribution of in-vitro diagnostics using molecular biology and immunological methods and selective media for detection of pathogens;  
distribution of medical devices in the field of blood pressure measuring, medical equipment and instruments including otoscopes, ophthalmoscopes, dermatoscopes, laryngoscopes, stethoscopes, ventilators, endoscopy, reflex and percussion hammers and tuning forks as well as patient monitoring systems in the field of anaesthesia, ECG, pulse oximetry and fetal monitoring, portable x-ray devices, scales, dental chair units and other examination devices with corresponding accessories

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016  
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-02-02  
Valid until 2027-02-01

Registration No. D1155300015  
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Stuttgart, 2024-02-02

  
Certification Body