

Certificate

We hereby certify the company

Andreas Hettich GmbH
Föhrenstraße 12
78532 Tuttlingen
Germany



with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Design, development, manufacture, distribution, and maintenance of laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for separating blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes

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 2025-10-25
Valid until 2028-10-24

Registration No. D1459300008
Report No. P25-00101-322726

Stuttgart, 2025-08-01



Certification Body



Sites included in the certification:

Location	Scope
Andreas Hettich GmbH Föhrenstraße 12 78532 Tuttlingen Germany	Design, development, manufacture, distribution, and maintenance of laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for separating blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes
Andreas Hettich GmbH Föhrenstraße 25 78532 Tuttlingen Germany	Maintenance and manufacture of parts for laboratory centrifuges for IVD applications and general laboratory purposes, centrifuges for the separation of blood components for transfusion purposes, and microbiological incubators for IVD applications and general laboratory purposes

Stuttgart, 2025-08-01



Certification Body