

CERTIFICATE

for a management system as per

ISO 13485:2016
EN ISO 13485:2016+AC:2016

Evidence of conformity has been furnished.

bertrandt

Bertrandt Medical GmbH
Birkensee 1, 71139 Ehningen / Germany

for the operating sites:
Im Weiherfeld 1, 65462 Ginsheim-Gustavsburg / Germany
Friedrich-Bergius-Ring 9, 97076 Würzburg / Germany

scope:

Scope of operating sites see appendix

Certificate registration No. **73 105 6750**

Certificate valid from 2023-04-01 to **2024-05-26**

Audit report No. 4355 6619



Dr. M. Parde

Release: Darmstadt, 2023-03-15
Certification body of TÜV Hessen
– Head of Certification body –

Translation of German original

ANNEX

belonging to Bertrandt Medical GmbH

site

scope

Im Weiherfeld 1
65462 Ginsheim-Gustavsburg
Germany

Development and verification services in the electromechanical medical device sector and development of medical device software on behalf of customers

Friedrich-Bergius-Ring 9
97076 Würzburg
Germany

Development services in the electromechanical medical device sector and development of medical device software on behalf of customers.

DIN EN ISO 13485:2016

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Deutsche
Akkreditierungsstelle
D-ZM-14137-01-01

Dr. M. Pawick

Release: Darmstadt, 2023-03-15
Certification body of TÜV Hessen
– Head of Certification body –

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