



Certificate

No. Q5 102326 0001 Rev. 00

Holder of Certificate: **Thora Tech GmbH**
Gutfleischstr. 3-5
35390 Gießen
GERMANY

Certification Mark:



Scope of Certificate: Design and development, production and distribution of monitoring- and ventilator systems

The provision of design and development services for respiratory and sleep diagnostic medical devices and relevant medical device software

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 102326 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_102326_0001_Rev_00)

Report No.: 713227351_2

Valid from: 2024-10-24
Valid until: 2027-10-23

Date, 2024-10-24

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Thora Tech GmbH**
Gutfleischstr. 3-5, 35390 Gießen, GERMANY

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monitoring- and ventilator systems

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