



Product Service

# Certificate

No. Q5 098327 0003 Rev. 02

**Holder of Certificate:** **Cortrium ApS**  
Erik Husfeldts Vej 7  
2630 Traastrup  
DENMARK

**Facility(ies):** Cortrium ApS  
Erik Husfeldts Vej 7, 2630 Traastrup, DENMARK

see Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Distribution,  
Service and Production of ECG Devices**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 098327 0003 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 098327 0003 Rev. 02)

**Report No.:** 713182601

**Valid from:** 2021-11-03

**Valid until:** 2024-03-18

**Date,** 2021-11-03

Christoph Dicks  
Head of Certification/Notified Body