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Zentralstelle der Länder  
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bei Arzneimitteln und  
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Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 098327 0004 Rev. 00**

**Manufacturer:** **Cortrium ApS**  
Erik Husfeldts Vej 7  
2630 Traastrup  
DENMARK

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

**Product Category(ies): ECG Devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 713132834

**Valid from:** 2019-03-12

**Valid until:** 2023-03-18

**Date,** 2019-03-12

Stefan Preiß

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