

Certificate No: 41319383  
Date: February 14, 2014  
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**Activity** Review of the Technical File according to MDD 93/42 EEC (Swedish implementation LVFS 2003:11) as amended by 2007/47/EC (Swedish implementation LVFS 2009:18).

**Review based on** European Guidance documents (MEDDEVs, NB-Meds and NBOG BPGs) and Intertek's procedures.

**Reviewed by** Ingrid Blidberg

**Review dates** December 3 2013 and January 20, February 14 2014.

**Location** Kista, Sweden

**Product** Segment CMR (Cardiovascular image analysis software)  
Class IIa

**Conclusion** The technical documentation for the above-mentioned product, including corrective actions, has been reviewed and found to contain the information prescribed in the regulations. The information has been found to be plausible and credible.

**Intertek Semko AB**  
Notified Body MDD



Hans Ericsson  
Certification Authority