

CE CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0906450  
Order No.: 123213

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15<sup>th</sup> December 2005 relating to medical devices pursuant to act no. 6 of 12<sup>th</sup> January 1995 relating to medical devices, transposing directive 93/42/EEC as amended by directive 2007/47/EC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: **Tenacore Holdings, Inc.  
647 E. YOUNG ST.  
SANTA ANA, CA 92705  
USA**

Device category: Fetal Transducers

GMDN code: See Appendix 1 to this certificate

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIb

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC as amended by directive 2007/47/EC, with the exemption of section 4.

Date of audit: 2009-02-24 & 2009-05-01

Date of the end of the validity: 2014-08-01

Nemko EC notification No.: 0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2009-07-21

Date of verification: 2009-07-21

Signature: Svein Grahnstedt  
MD PhD Senior Lead Auditor

Signature: Frank Skarpsno  
Senior Lead Auditor / Principal Engineer

**CE 0470**