

# EC Certificate

## PRODUCTION QUALITY ASSURANCE

### Directive 93/42/EEC on Medical Devices, Annex V

Certificate Number  
41319333

Initial Certification Date  
March 28, 2014

Certificate Valid from  
March 28, 2014

Certificate Expiry Date  
March 27, 2019

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

*Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.*

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We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements - has been carried out following the requirements of the Swedish national legislation, LVFS 2003:11, to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

#### Organization:

### Aggero Medtech AB

Ola Hanssonsgatan 4, SE-11252, Stockholm, Sweden

#### Product Category:

Device for measuring of Muscle Tone in Spastic Muscles,  
Class I(m)

For further identification of the products covered, see the MDD product list/product schedule.

March 28, 2014

Signed date



Hans Ericsson, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden