

Certificate No: 41319383
Date: March 20, 2015
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Medviso AB
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Sweden

Purpose Assessment of the application dated February 18, 2015 to add a new product to be included in your certified quality system according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile/ Measuring	GMDN code (not mandatory)
Software for Medical image analysis	Segment CT (Cardiovascular image analysis software)	Ila	No	-

Conclusions/Decisions The products are similar to previously accepted products. The application has been accepted and the product/s can be added. Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Follow-up assessments At the next audit your auditor may follow-up on the implementation of the new products in the Quality system.

Appeals Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD



Joakim Jemseby
Certification Authority