MDD – Product Decision

Certificate No: 41319383
Date: October 16, 2018
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Medviso AB
Attn: Helen Fransson
Griffelvägen 3
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Sweden

Purpose

Assessment of the notification dated October 01, 2018, to add product to 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	GMDN code (not mandatory)
Software for Medical image analysis	Segment 3DPrint	IIa	No	

Conclusions/Decisions

The product is similar to previously accepted products. The notification has been accepted and the product 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 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

Peter Nermander
Certification Authority MDD