MDD – Decision Report

Certificate No: 41317999-01, 41310336-01
Date: December 9, 2016
Handled by: Caroline Åman
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Apotek Produktion & Laboratorier AB
Trade name: APL
Att: Josip Zeljko Tucak
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141 75 Kungens Kurva

Purpose	Five year extension assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II and Annex VI.
Scope of assessment	(41317999-01, Annex II) - Lubricants - Cleaning and disinfectant liquid for vein catheters - Additive to haemodialysis concentrate - Products for disinfection of medical devices - Dental treatment products, invasive or non invasive, class Is and IIb (41310336-01, Annex VI) Dosing devices class I with a measuring function for oral administration of medicinal products, Class I
Certificate Valid from	December 9, 2016
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II and VI will be issued. The Certificates is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Mats Premfors
Certification Authority MDD