EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41315837-02

Initial Certification Date
June 12, 2007

Certificate Valid from
June 13, 2017

Certificate Expiry Date
June 12, 2022

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.

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

SWEDAC ACKREDITERING

Ackred. nr 1003
ISO/IEC 17021

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Sendoline AB

Box 7037, Tillverkarvägen 6, SE-187 66 Täby, Sweden

Product Category:

- Endodontic Medical Devices

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

June 8, 2017
Signed date

Bob Andersson, Certification Authority MDD
Intertek Semko AB, Kista, Sweden