

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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:

Dentatus AB

Main Site: Finspångsgatan 42 SE-163 53 Spånga, Sweden

Product Category:

- Dental instruments
- Dental Implants
- Dental Posts
- Dental Implant procedure kits and accessories

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

Certificate Number:

41319232-02

Initial Certification Date:

12 April 2013

Certificate Valid from:

08 August 2018

Certificate Expiry Date:

12 April 2023



Akkred. nr 1003
ISO/IEC 17021


Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

16 August 2018

Signed Date

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

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.

