

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41315325-01

Initial Certification Date
December 21, 2005

Certificate Valid from
December 22, 2015

Certificate Expiry Date
December 21, 2020

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.

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.

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Ackred. nr 1003
ISO/IEC 17021

Organization:

S.S. White Burs, Inc.

1145 Towbin Avenue, Lakewood, New Jersey 08701, USA

Product Category:

Dental devices
- Rotary cutting tools
- Diamond abrasive instruments
- Dental abrasive polishers

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

December 21, 2015

Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden