intertek
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EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production 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 V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Medental International

Main Site: Jose Ma. Bustillos NO. 28-BIS, Col. Algarin, Mexico City, Distrito Federal 06880, Mexico

Product Category:

- Dental materials

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

*Previously certified by Intertek AMTAC (NB0473) to date 29 June 2018

Certificate Number:
41377502-00

Initial Certification Date:
19 May 2010*

Certificate Valid from:
29 June 2018

Certificate Expiry Date:
18 May 2020

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

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

29 June 2018
Signed Date

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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.