



EC Certificate - Full Quality Assurance System

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

USA

No. Issued To: CE 598352 Zest Anchors, LLC also DBA Zest Dental Solutions and Danville Materials 2875 Loker Avenue East Carlsbad California 92010

In respect of:

The design and manufacture of dental implant systems, abutments, restorative components, composite restorative materials, dental adhesive materials, dental air abrasion systems and etch system for the dental industry.

Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of dental endoscope sterile sheaths.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk -Medical Devices

First Issued: 2013-06-18

Date: 2018-06-20

Expiry Date: 2023-06-18

...making excellence a habit." Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.