



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 08 07 67012 001

Manufacturer: D.B.I. AMERICA CORPORATION
254 Crystal Grove Blvd
Lutz FL 33548
USA

EC-Representative: Maecolux S.A.
32 Demier sol Residence Dali
G.D. Luxembourg
25436 Luxembourg
LUXEMBOURG

Product Category(ies): Dental Piezo Ultra Sonic Scaler;
Combination Dental Piezo Ultra
Sonic Scaler with Dental Electric Motor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: DM804523-102

Valid until: 2013-10-22

Date, 2008-10-23

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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Facility(ies):

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254 Crystal Grove Blvd, Lutz FL 33548, USA**



**JANE E. MCNAMARA
Notary Public
Commonwealth of Massachusetts
My Commission Expires
November 19, 2015**