

CE CERTIFICATE OF CONFORMITY
WITH EUROPEAN DIRECTIVE



Certificate No.: EU1212404
Order No.: 227702

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: Abrasive Technology, Inc.
8400 Green Meadows Dr. N.
Lewis Center, OH 43035
USA

Device category: See Appendix 1 to this certificate

GMDN code: See Appendix 1 to this certificate

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.

Date of audit: 2012.06.25-29, 2012.07.06

Date of the end of the validity: 2017.11.25


Nemko EC notification No.: 0470


Remark: This certificate replaces certificate EU1105418 dated 2011.11.11

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2012.12.14

Date of verification: 2012.12.14


Signature: Lars M. Forssander
Lead Auditor / Principal Assessor


Signature: Roy I. Holland
Lead Auditor / Principal Assessor

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Device category: See below


Appendix 1: Page 1 of 1

The certificate referred to above includes the following devices/models:

Devices category	GMDN code
Drill	16669
Diamond Podiatry Bur	10522
Dermabrader Diamond	10522
Dental Diamond Instruments	16670
Diamond Polishing Gel	16670
Diamond Polishing Gel Mandrel	35170
Diamond Polishing Gel Felt Applicators	16184
Diamond Polishing Gel Kit	16670
Fiber composite post	38609
Fiber composite post kit	38609
Fiber composite dental rotary instrument	58073

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