



EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 281071-2018-CE-NOR-NA-PS Rev 2.0

Project No.: PRJC-471312-2013-MSL-NOR_MDD

Valid Until: 25 February 2024

This is to certify that the quality system of:

Abrasive Technology, Inc.

8400 Green Meadows Drive, North

Lewis Center, OH 43035

USA

For design, production and final product inspection/testing of:

Active Dental Devices and Active surgical devices

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 17 April 2021

For the issuing office:
**Notified Body 2460
DNV Product Assurance AS**



Palani Damodharan
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	20 February 2019
1.0	Change in EU Representative	16 October 2019
2.0	Scope Extension (in bold)	17 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Active Dental Devices Drills	Two Striper® Dental Root Canal Drills	Ila
Active Dental Devices Rotary Dental Diamond Instrument or Bur	Two Striper® and Prodia® Dental Diamond Instruments	Ila
Active Dental Devices Composite Dental Bur	Two Striper® and Stainbuster® Dental Burs	Ila
Active Surgical Devices Diamond Podiatry and Dermatology Burs	Two Striper® Diamond Podiatry and Dermatology Burs	Ila
Fiber Composite Dental Posts	Two Striper® Carbopost® Dental Posts Two Striper® Snowpost® Dental Posts Two Striper® Snowlight Post® Dental Posts	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Abrasive Technology, Inc.	8400 Green Meadows Drive, 43035, Lewis Center, USA



Certificate No.: 281071-2018-CE-NOR-NA-PS Rev 2.0
Place and date: Høvik, 17 April 2021

EU Representative

MedNet GmbH, Borkstrasse 10, 48163 Münster, Germany



Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
281071-2018-CE-NOR-NA-PS Rev 2.0

Valid Until:
25 February 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Abrasive Technology, LLC

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

The legal name of a site has changed.

Sites covered by certificate (replaces information on certificate)	
Site Name	Site Address
Abrasive Technology, LLC	8400 Green Meadows Drive, North Lewis Center, OH 43035 USA

Appendix History -		
Revision	Description	Issued Date
0.0	Change in Company Name to Abrasive Technology, LLC	11 January 2022

Place and date:
Høvik, 11 January 2022



For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer