EC Certificate
Full Quality Assurance System

Certificate No.:
281071-2018-CE-NOR-NA-PS Rev. 1.0

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, 16 October 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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

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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	2019-02-25
1.0	Change in EU Representative	2019-10-16

Products covered by this Certificate:

Product Description	Product Name	Class
Active Dental Devices Drills	Two Striper® Dental Root Canal Drills	IIa
Active Dental Devices Rotary Dental Diamond Instrument or Bur	Two Striper® and Prodia® Dental Diamond Instruments	IIa
Active Dental Devices Composite Dental Bur	Two Striper® and Stainbuster® Dental Burs	IIa
Active Surgical Devices Diamond Podiatry and Dermatology Burs	Two Striper® Diamond Podiatry and Dermatology Burs	IIa

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

EU Representative

MedNet GmbH	**Borkstrasse 10, 48163 Münster, Germany**

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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate