

2019

## CERTIFICATE OF REGISTRATION

*This certifies that:*

**INHALO DSI HUNGARY KFT.  
Vizonto Utca 4  
Erd Pest, HUNGARY 2030**

is registered with the U.S. Food and Drug Administration for FY 2019 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:

**3014872119**

U.S. Agent:

**Registrar Corp**

144 Research Drive, Hampton, Virginia, 23666, USA

Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*



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## Certification

February 11, 2019

Patrick Holota

INHALO DSI HUNGARY KFT.

Vizonto Utca 4

Erd Pest, HUNGARY 2030

Re: U.S. FDA Registration

Good Day:

We are pleased to provide you with your company's U.S. Food and Drug Administration (FDA) Establishment Registration Number, found on the attached Certificate of Registration issued by Registrar Corp. Your establishment's registration with the U.S. FDA is now active. If there are any errors in the registration on the Certificate, please notify us in writing, preferably by fax so that we may correct the problem for you.

Registrar Corp also will send you a color copy of your Certificate of Registration by email. You may wish to use this electronic version to forward copies of your company's Certificate of Registration to your customers and suppliers so they are aware that your company has complied with the U.S. registration requirements. Please note, however, that pursuant to 21 CFR § 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." This means the certificate does not denote endorsement or approval by the U.S. FDA, and it should not be used to suggest such an inference.

The registration applies only to the establishment identified by the Certificate. If your company's operations change, you may be required to submit a device listing. Similarly, if your firm moves locations, or obtains an additional location, the new locations must be registered also. We will be pleased to assist anytime you need device listings or establishment registrations.

We look forward to assisting you with additional U.S. FDA compliance issues in the future. Please contact us if you have any additional questions.

Sincerely,

Russell K. Statman

Executive Director

*Certificates of Registration issued by Registrar Corp provide confirmation to industry that you are fulfilling FDA Registration requirements. FDA does not issue or recognize Certificates of Registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*