



OGYÉI

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Case No.: **OGYÉI/13376-3/2018**

Subject: Certificate for third countries

Consultant: Gábor Szlobodnyik

FREE SALES CERTIFICATE

On request of the the **INHALO DSI Hungary Kft.** (2030 Érd, Vízöntő utca 4., Hungary) the National Institute of Pharmacy and Nutrition hereby certifies, that on the basis of information provided, the medical device(s) named below and detailed in the attachment (if applicable), which is/are manufactured by the above economic operator, has/have been affixed with the CE mark under the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices and/or the Council Directive 93/42/EEC concerning medical devices (as amended) which was transposed into Hungarian national law [decree No. 8/2003. (III. 13) of the Minister of Health, Social and Family Affairs on in vitro diagnostic medical devices and /or decree No. 4/2009 (III. 17) of the Minister of Health on medical devices, as amended] may be freely sold in all member states of the European Economic Area (EEA) including Hungary.

DSI INHALO Nasal Inhaler

DSI INHALO Bronchial Inhaler

INHALO removable salt holder

This certificate has been issued to Hungarian exporters for use in non-EU (EEA EFTA) third countries to support the application for permission of placing the above mentioned devices on the market.

A Free Sales Certificate should not be taken as a Government endorsement of any product that is referred to on the certificate or its attachment.

Budapest, 14 March 2018

On behalf of **Dr. Csilla Pozsgay**

Director General



Péter Bunyitai

Head of Department



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File No.: 11024/H/2806/2018.
(licence to act in English No.: XX-ISZFO/1111/2011)

---I hereby certify that this document hereunto annexed is a true and faithful copy (in respect of its content) of the 1, i.e. one page document with original signature, long stamp and round stamp, presented before me, as original.-----

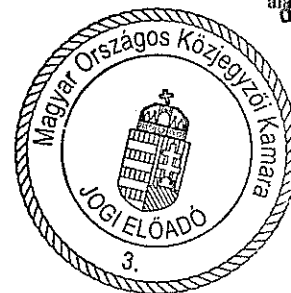
---Budapest, this 23rd (twenty-third) day of April in the year of 2018 (two thousand and eighteen).-----



Dr. Vadász, Zsuzsanna
Notarysubstitute

2018/3477
A fenti aláírás és bélyegzőlenyomat
hitelesül.

Budapest, 2018 APR 23.



aláírás
Dr. Bárdos Judit
jogi előadó