



DECLARATION OF CONFORMITY OF LIQUA PRODUCTS

Dear valued business partner,

we would like to inform you about Ritchy's position to in our opinion misleading RAPEX alert A12/0906/18 submitted on 9.7.2018 by Health Service Executive (HSE), an Irish Authority in charge of e-cigarette products. RITCHY considers this alert as an abuse of the RAPEX system, which is to be used for notification about dangerous non-food products posing a risk to health and safety of consumers and would like to ensure our trade partners that our products are in compliance with TPD/ CLP related regulatory requirements.

As stated in the alert and similarly confirmed by HSE prior to the filling of the alert, the major and only problem HSE has with our product is **an absence of a leaflets in the packaging required by the Irish regulations (despite all mandatory information are stated on packaging)**

In the past weeks we were in communication with HSE, trying to explain them our interpretation of TPD related law, based on guidance from several members states such as the UK Medicines and Healthcare products Regulatory Agency (MHRA) which states: *Where all the required leaflet information can fit on the unit pack and other labelling within the pack without loss of legibility to the consumer, our interpretation of the TPD is that the packaging can be considered to include the leaflet, and a separate leaflet insert is not required.*¹

Some EU member states regulators such as the MHRA in UK provided a clear guidance on how to proceed, others such as HSE did not comment about technical standards of leaflet even when asked by us. Therefore in the past we proceeded with placing all mandatory information in legible format on the unit pack in the form of sticker. As such the user has all information required by TPD and CLP even more visible than if inserted in a box as a leaflet. Unfortunately our approach differs from the interpretation and requirement of HSE, which prefers to have all the information on a leaflet inside a box.

We were cooperating in the past weeks with HSE to take all measures required by HSE to make all products compliant and at this moment our products on Irish market are compliant. The more disappointed we are by the decision of HSE to file a RAPEX alert and the form of notification which is misleading and raise concerns about health and safety of our products

¹ <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products>

Ritchy EU, s.r.o.

Karla Engliše 519/11, 150 00 Prague 5, Czech Republic, European Union

www.ritchy.com | info@ritchy.com

Tel.: (+420) 225 067 840 | IČ: 014 93 299 | DIČ: CZ 014 93 299



We would like to assure you that apart from missing leaflet our products do not pose any risk to health and safety to consumers and fulfil all local regulation requirements included in EUTPD. Our products went in past years through several checks of authorities in Denmark, Belgium, Germany including lab testing and always were confirmed to be compliant.

We have as well proceeded with appeal to enforcing Authorities. RAPEX system serves for notification about dangerous non-food products posing a risk to health and safety of consumers. We believe a missing leaflet (consumer has all information required by TPD/ CLP available on box) is not reason to notify our product into this system.

In case of further questions, please feel free to contact us on compliance@goritchy.com

In Prague, 12th of July 2018

RITCHY
RITCHY EU s.r.o.
Karla Engliše 519/11, 150 00 Praha 5
IČO: 01493299
DIČ: CZ01493299

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Vit Straka, Compliance Director

Ritchy EU, s.r.o.

Karla Engliše 519/11, 150 00 Prague 5, Czech Republic, European Union

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