

Insta Fill - Compliance Page

Insta Flow Compliance Statement in Adherence to Product Requirements Regulation 36

We hereby present a detailed analysis of the Insta Flow product's compliance with the stipulated requirements under Regulation 36 as provided. Each requirement has been meticulously addressed, highlighting how Insta Flow not only meets but indeed exemplifies the standards set forth.

1. *Regulation 36 (1): *General Compliance

The Insta Flow system is designed and manufactured with the express purpose of adhering to all relevant regulations. As such, no part of its design or function contravenes the requirements outlined in paragraphs (2) to (8) of Regulation 36.

2. *Regulation 36 (2): *Volume of Nicotine-containing Liquid

- Insta Flow's device tank is a pre-filled 2ml tank, adhering to stipulation (2)(b).
- Furthermore, the dedicated refill container provided with the product has a volume of 10 millilitres, in line with stipulation (2)(a). It's imperative to note that this refill container is not attached to the device at the point of sale and is equipped with a child safety cap.

3. *Regulation 36 (3): *Tank Capacity

The Insta Flow device's tank, as already mentioned, possesses a 2ml capacity. This complies with the stated requirement that the capacity of the tank of a refillable electronic cigarette must not exceed 2 millilitres.

4. *Regulation 36 (4): *Nicotine Concentration

Insta Flow guarantees that any nicotine-containing liquid presented for retail sale in its devices does not contain nicotine in excess of 20 milligrams per millilitre, fully adhering to this regulation.

5. *Regulation 36 (5): *Contents and Purity of the Liquid

The e-liquid contained within the Insta Flow system:

- Does not contain any prohibited additives such as vitamins or colourings.
- Is manufactured using only high-purity ingredients.
- Only contains substances that have been duly notified under regulation 31, save for any technically unavoidable trace levels.
- Ensures no ingredient, other than nicotine, poses any risk to human health in either heated or unheated forms.

6. *Regulation 36 (6): *Consistent Nicotine Delivery

Insta Flow has been engineered to deliver a consistent dose of nicotine under normal conditions of use, ensuring user satisfaction and safety.

7. *Regulation 36 (7): *Safety and Integrity

The design and functionality of the Insta Flow system prioritise safety:

- It's designed to be child-resistant, featuring a discreet on-off switch for child safety.
- The system is tamper-evident, providing visible evidence if the product or its packaging has been breached or opened, in compliance with Regulation 36 (9).
- The robust construction of both the device and the refill container offers protection against breakage and leakage.

8. *Regulation 36 (8) & (10): *Refilling Mechanism

A key feature of the Insta Flow system is its leak-free refilling mechanism. The refill container, once attached to the device, acts as a docking system, releasing refill liquids into the tank only when the two are connected, as per the stipulation in 36(10)(b). This ensures a seamless, spill-free experience for the user, with the added assurance that detaching the refill container is also free from accidental leakage, thanks to its auto-seal feature.

9. *MHRA Guidance*:

Addressing the additional guidelines presented by MHRA:

- The Insta Flow system does not utilise or provide any non-compliant extender/replacement tanks.
- It doesn't rely on non-essential components to alter tank size.
- It isn't a "squonker" and doesn't possess any container with a capacity over 2ml.
- All components of the Insta Flow system are compliant with regulations and are duly registered with MHRA.

10. *Noteworthy Features for Emphasis*:

- The system can operate independently without the refill container, offering flexibility to the user.
- It is not a reservoir, extension of a tank, or a squonker that can be squeezed. Instead, it's a dedicated refill container requiring manual intervention (held facing downwards for 30 seconds) to fill.

In conclusion, the Insta Flow product has been conscientiously developed to uphold and respect all the standards and requirements laid out in Regulation 36. We are confident in the product's compliance and stand ready to address any additional queries or provide further clarifications as needed.

Insta Fill EC ID

EC-ID NUMBER	PRODUCT NAME
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00001	INSTAFILL - BLACKCURRANT APPLE - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00002	INSTAFILL - BLUEBERRY FUSION - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00003	INSTAFILL - FIZZY CHERRY - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00004	INSTAFILL - FRESH MINT MOJITO - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00005	INSTAFILL - GUMMY BEAR - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00006	INSTAFILL - BANANA ICE CREAM - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00007	INSTAFILL - LEMON LIME - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00008	INSTAFILL - MIX BERRY FUSION - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00009	INSTAFILL - PINEAPPLE ICE - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00010	INSTAFILL - POLAR MINT - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00011	INSTAFILL - RASPBERRY LEMONADE - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00012	INSTAFILL - SOUR BLUE RASPBERRY ICE - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00013	INSTAFILL - STRAWBERRY ICE - 3500puffs 20mg Mesh Coil - KIT
<i>Device:</i> 09839-23-00015 - <i>E-liquid:</i> 09839-23-00014	INSTAFILL - WATERMELON CANDY ICE - 3500puffs 20mg Mesh Coil - KIT

Insta Fill Letters



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13 June 2023

Re: Insta Fill Device Compliance

To Whom It May Concern:

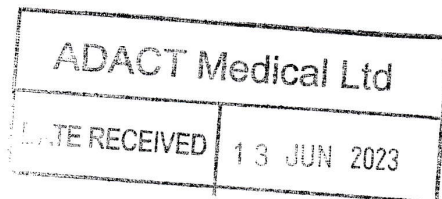
In my position as the Chief Regulatory Officer of ADACT Medical and a recognised long standing expert in ENDS regulatory standards for The Tobacco and Related Products Regulations 2016 (TRPR) and the Tobacco Product Directive (TPD) in Europe and the UK, I have reviewed the Insta Fill device for compliance.

This review was undertaken to ascertain the compliance of the device with relation to a 2ml tank capacity for a device with a capability of using a dedicated refill container. I have found the device to be fully compliant with the regulation. A summary of the review is given below.

- The product has a single tank of 2ml volume, and can dock with a dedicated 10ml refill container, this has the potential to be viewed as 10ml tank, such as so called 'squonk boxes'
- However this is not a tank as it does not operate as part of the vaping system is not part of the device and the device that can operate without it.
- The regulations allow for a dedicated refill container of up to 10ml, which is different from 10ml bottles.
- The device enables the consumer to refill their tank from the dedicated refill container.
- The refill container is not present in the device at the point of sale.
- The regulation on filling nibs for 10ml bottles does not apply to the dedicated refill container which is not covered by this regulation.

In my conclusion this device is fully compliant with the requirements of the legislation.


Damien Bove
Chief Regulatory Officer
Adact Medical





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22 June 2023

Dear Sir / Madam

RE: INSTAFILL Vaping Device & Dedicated Refill Container

Arcus Compliance Ltd have been commissioned to review the INSTAFILL vaping device and the associated INSTAFILL dedicated 10ml refill container to assess potential regulatory compliance in line with 'The Tobacco and Related Products Regulations 2016 (TRPR)' and the 'Tobacco Product Directive (TPD)' in the UK and Europe respectively. We have examined the prototype device and refill container, investigating in-depth the patented design features and can confirm that it is our opinion that the design and features of the device and refill container will conform with the regulations of TPD and TRPR on submission.

The prototype and product design features have additionally been presented to the lead trading standards officer of our Primary Authority Partnership (PAP) and initial indications support our conclusion of compliance. A letter of assurance confirming product compliance from the PAP is pending and co-dependent on the products achieving 'submitted notified' status with the MHRA in the UK.

Concurrent work to complete 'submitted notified' status in the UK and specific EU Member states is ongoing and there are no indications that the device or refill container will not achieve the status in the very near future.

In conclusion the prototype device design and dedicated refill container are assessed to meet the regulatory standards for the UK and Europe.

Robert Sidebottom

Robert Sidebottom
Managing Director
Arcus Compliance Ltd.

Guidance for Trading Standards: Instafill Product

Introduction

The Vaping Expert Panel were asked for their views on whether the Instafill product comply with the product requirements of regulation 36 of the Tobacco and Related Products Regulations 2016.

The following guidance has been prepared with the assistance of the Department of Health and Social Care Legal team.

Instafill Product

Key Features USP



Product description

The product has a permanent, empty 2ml tank and a separate dedicated refill container with 10ml of nicotine containing liquid. The 10ml refill container is inserted into the device and used to fill the 2ml tank with the nicotine liquid, as required. The refill container is therefore, not a tank.

Advice

This product is different from squonkers where the refill bottle in effect replaced the role of the tank.

The product is an e-cigarette with an empty 2ml tank with a dedicated refill container with 10ml of nicotine-containing liquid, as permitted by regulation 36(2)(a).

It is a more difficult argument that permanently attaching the refill container to the product increases the overall tank size beyond 2ml.

Therefore, this product appears to be compliant with Regulation 36(2).

In offering this advice the Chartered Trading Standards institute wishes to make it clear that: Legislation may change over time and the advice given is based on the information available at the time the guidance was produced. It is not necessarily comprehensive and is subject to revision in the light of further information. Only the courts can interpret statutory legislation with any authority. This advice is not intended to be a definitive guide to, nor substitute for, the relevant law. Independent legal advice should be sought where appropriate. It is for individual local authorities themselves to decide what action, if any, they take in relation to these products.

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Robert Jappie
Partner

23rd October 2023

Dear Sirs

**Re: AKS HOLDING LTD - LETTER OF COMPLIANCE
VAPING COMPLIANCE ADVICE**

I am a solicitor qualified in England & Wales. I am instructed AKS Holding Ltd in relation to their UK vaping business. I provide regulatory and commercial support for their business endeavours.

Executive Summary

- AKS Holding is importing and distributing a new Vaping Device in the UK. The device is the Instafill Vaping Device & Dedicated Refill Container – details of which are attached herewith.
- I have reviewed the product and compared the specifications with the provisions of The Tobacco and Related Products Regulation 2016 (TRPR) and the EU Tobacco Products Directive (TPD). I have also seen the assessment prepared by Arcus Compliance – an established and well-respected Vaping Compliance agency.
- I can confirm that our initial position is to agree with the assessment from Arcus Compliance. The product complies with the 2ml tank limitations stipulated by the regulations (TRPR). The refill tank system does not breach the regulations. Therefore, in my view the product can be imported into the UK and lawfully distributed/sold in accordance with UK regulations.

Brussels / Dusseldorf / Hamburg / London / Manchester / Munich / Paris / Shanghai / Silicon Valley