



UKVIA Guide to Regulatory Compliance

Regulatory guidance for a high quality and
responsible UK vaping sector

The UK vaping industry strives for the highest levels of product quality, manufacturing, and safety standards.

This guide has been produced by members of the UKVIA's Standards Committee to ensure that regulators and the public health community have absolute confidence in promoting vaping products to adult smokers, and that adult smokers are encouraged to make the switch to vaping, as an effective and less harmful alternative. This document sets out the quality and standards principles that reflects current regulations for enhance compliance across the category.

Where national regulations exist, these take precedence. In these cases, this document may provide supplementary guidance in addition to national regulations. Businesses should check for any specific requirements for the country they intend to supply to.

This guidance covers: product manufacturing, devices and accessories, consumable ingredients and components, product performance and new product launches.

Product manufacturing

- **Technical dossiers:**

- » A technical dossier should be produced and maintained and approved by the competent person/authorised representative(s) of the company for each device manufactured and reflect the Tobacco and Related Products Regulations (2016) (TRPR)/Tobacco Products Directive (2014/40/EU) (TPD) and, in the case of liquids, the requirements of the Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation (EC) No 1272/2008). The dossier should reflect the standards expected in the country in which the manufactured device is being delivered to.
- » A compliance file should be produced and maintained and approved by the competent person/authorised representative(s) of the company for each e-liquid manufactured. The file should reflect the standards expected in the country in which the manufactured e-liquid is being delivered to.
- » Both should contain information relating to the manufacturing and quality control processes and should be made available to regulatory/inspection officers on request.

- **Quality management system & process control:** Device and consumable components manufacture to be subject to appropriate management systems as detailed in ISO 9001:2015 or another appropriate standard.
- **Certifications:** Device and consumable components to be certified compliant to specification by appropriate Certificate of Compliance and be supported by component batch traceability linked to a URL on every packaging unit. Quality assurance processes in place to confirm e-liquids and devices are manufactured to product specification.
- **Quality Control:** Devices should carry a batch number and date of manufacture. Quality of manufacture should be checked prior to assembly and once assembled. Every device should undergo a start-up test before it is packed and shipped.

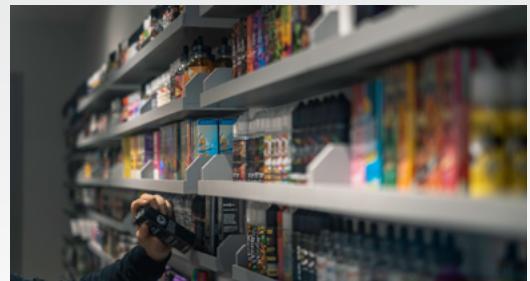


Devices and accessories

- Devices, batteries, and accessories meet requirements of the latest versions of the relevant electrical safety standards. In the UK, the UKCA marking came into effect on 1st January 2021. Business will still be able to use the CE marking until 1 January 2023 in most cases.
- Risk assessments to be performed, taking in to account the normal and reasonably foreseeable uses of the devices throughout their lifetime(s). Risks should be communicated to consumers as a warning, either as part of the labelling, packaging, or accompanying product instructions.

Consumable ingredients and components

- Only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. For e-liquids, nicotine meets the purity requirements that are outlined in the European (EP) or US (USP) Pharmacopoeia standards for nicotine. E-liquid excipients (propylene glycol and glycerol) also to meet EP or USP Pharmacopoeia standards. Other consumer ingredients are at a minimum approved for use in food in the EU or other regulatory jurisdictions, as appropriate, or approved at CEN level.
- E-liquid suppliers should be able to provide certification analysis. The following ingredients should be



- Nicotine suppliers should be able to provide certification analysis. The following ingredients should be excluded:
 - » vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
 - » caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
 - » additives having colouring properties for emissions;
 - » for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake;
 - » additives that have CMR properties in unburnt form;
 - » Substances classified with specific target organ toxicity for the respiratory tract (STOT SE 1,2,3);
 - » Respiratory sensitisers;
 - » additives in quantities that increase, to a significant or measurable degree, the toxic or addictive effect or CMR properties of the product when it is consumed;
 - » Specific ingredients: Diacetyl, Acetyl Propionyl, Diethylene Glycol, Ethylene Glycol, Formaldehyde, Acetaldehyde and Acrolein;
 - » Metals, including cadmium, chromium, iron, lead, mercury, and nickel; and
 - » Preservatives liable to release formaldehyde.

excluded:

- Toxicological Risk Assessments should be undertaken by an appropriately qualified person to determine suitability of ingredients via inhalation and if exposures may result in adverse effects to the user.

- Notification by a producer who supplies or intends to supply electronic cigarettes or refill containers should produce toxicological data regarding the product's ingredients (including in heated form) and emissions, referring in particular to their effects on the health of consumers when inhaled and taking into account, amongst other things, any addictive effect.
- E-liquids are subject to appropriate quality control checks prior to placing on the market and ensure nicotine content of each batch manufactured is in accordance with specification.
- E-liquids are analysed for potential undesirable constituents that may form over time. Corrective actions should be taken should they be present above toxicologically supportable levels.
- E-liquid storage containers and bottles must be compatible with nicotine, i.e., potential toxic monomers commonly used in the production of plastics should not leach into the e-liquid formulation.
 - » Bottle manufacturers should be able to provide extractable and leachable certification analysis.
- Traceability to be ensured through elements such as batch ID or production date with each batch of e-liquid individually tested against specification before release.

Product performance

- The nicotine concentration should be measured using a defined testing regime. Diethylene glycol and diacetyl (possible e-liquid contaminants), formaldehyde, acetaldehyde and acrolein (thermal degradation products) and trace metals (as an indicator of coil integrity) should also be measured or confirmed absence from suppliers' certificate of analysis.
- For vaping products with pre-filled cartomizers, the testing is to be conducted on the product as sold to the consumer.
- For e-liquids in refill bottles, the testing is to be conducted under normal use conditions using a commercially available refillable vaping product. The brand and name of the device used, power output, nicotine content, coil rating and airflow to be stated in the test report.
- For refillable vaping products, the testing is to be conducted using a defined commercially available e-liquid or ISO standard test liquid. The brand and name of the device used, power output, nicotine content, coil rating and airflow to be stated in the test report.
- If the device or e-liquid is substantially modified, a producer who supplies or intends to supply electronic cigarettes or refill containers must notify the MHRA in accordance with TRPR regulation.

New product launches

- Producers of new e-cigarette and refill container products must submit a notification to the MHRA six months before they intend to put their product on the market in Great Britain and/or Northern Ireland. Once notification has been published on the MHRA website producers can launch the product in the notified region. If notification has been published, producers do not need to wait for the remainder of the 6-month period to elapse before they place the product on the market in the notified region
- The notification to include product specifications and ingredients as per the TRPR regulations.
- Product classification to be based on both the consumable component and mechanism of use and must be a separate category distinct from tobacco products.

The screenshot shows a web-based application interface for product submission. At the top, there are navigation links: HOME, PIP, PUDR, MHRA-GMCP, ECG, and a search bar. Below the navigation is a search form with fields for 'Submitter Name', 'Brand Name', 'Brand Sub Type Name', and 'Product Type'. A dropdown menu for 'Product Type' is open, showing options like 'ELECTRONIC CIGARETTE', 'REFILLABLE', and 'OTHER'. A note below the search form states: 'Data from 1st to the Northern Ireland published products set from January 1st 2001 and all published products prior to December 31st 2000'.

Submitter Name	Product ID	Brand	Brand Sub Type Name	Product Type	Published Date
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00001	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00002	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00003	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00004	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00005	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00006	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00007	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00008	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00009	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00010	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00011	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
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BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00117	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00118	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00119	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00120	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00121	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00122	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00123	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00124	DABCO	• DABCO NIKON X100	ELECTRONIC CIGARETTE - DISPOSABLE	1/1/2000
BARDEN-DINE TECHNOLOGY COMPANY LIMITED	00125	DABCO	• DABCO NIKON X100		