

Manufacturer Declaration of Conformity with TGA Standards for Nicotine Vaping Products

Sponsor	FROM THE FIELDS AUSTRALIA PTY LTD ABN: 16 635 358 637	
Distributor	FROM THE FIELDS PHARMACEUTICAL PTY LTD ABN: 39 662 953 826 Wholesale Dealer's License #: 2022-87270	

This declaration is made to confirm conformity of FROM THE FIELDS AUSTRALIA's Nicotine Vaping Products with:

- Therapeutic Goods (Standard for Nicotine Vaping Products) Order 2021 (TGO 110); and
- The microbiological standards for medicines outlined in section 11 (1) of Therapeutic Goods (Microbiological Standards for Medicines) Order 2018 (TGO 100).

FROM THE FIELDS AUSTRALIA Nicotine Vaping Products (NVP)		
WILD BY INSTINCT PODs	1ml x 0mg/ml • Tobacco, Mint, Mango, Apple	
	1ml x 18mg/ml (Nic SALT) • Tobacco, Mint, Mango, Apple	
	1ml x 50mg/ml (Nic SALT) • Tobacco, Mint, Mango, Apple	
WILD BY INSTINCT Disposables	2.4ml x 0mg/mlMango Ice, Blueberry Ice, Crushed Fruit, Watermelon Ice	
	2.4ml x 50mg/ml (Nic SALT)Mint, Mango, Mango Ice, Blueberry Ice	
WILD BY INSTINCT E-Liquids	10ml x 18mg/ml (Nic SALT)	
	10ml x 36mg/ml (Nic SALT)	
	30ml x 50mg/ml (Nic SALT)Strawberry, Mango, Menthol, Berries, Caramel	
	50ml x 0mg/ml • Strawberry, Mango, Menthol, Berries, Caramel	
	60ml x 6mg/ml (freebase Nic) • Strawberry, Mango, Menthol, Berries, Caramel	

This declaration of conformity is issued under the sole responsibility of the Sponsor.

The Sponsor declares that the confirmation is in line with internal quality management systems (QMS) of From The Fields and independently tested by an ISO/IEC 17025 (CNAS-CL01 Accreditation Criteria for the competence of Testing and Calibration Laboratories) third party laboratory.

Signed on behalf of FROM THE FIELDS AUSTRALIA PTY LTD and FROM THE FIELDS PHARMACEATICAL PTY LTD

Paul Gerza

Chief Product Officer: Paul Gerza

Date: 01/01/2023

Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 and related matters

TGO 110 Requirement	Requirement detail	WILD BY INSTINCT compliance
Types of records that must be kept	 Copies of the labels of the product showing the information required under TGO 110 Records showing the design of the packaging used for the product and how it meets the child-resistant packaging requirements in TGO 110 Evidence that the product conforms to each of the Ingredient requirements in TGO 110, 	✓ Compliant
Labelling of nicotine vaping products	 To comply with the labelling requirement, each piece of information must be either included on, or attached to, the container or primary pack of the product, or set out in information supplied with the product Ingredient list the name of the active ingredient in the product (which must only be nicotine in base and/or salt form(s)). For nicotine salt products, the particular type of each nicotine salt in the product must be listed for flavoured products, either the word "flavour", or a description including the word "flavour" (e.g. "cherry flavour"), or the name of each ingredient in the flavour the names of all of other excipient ingredients Nicotine concentration for nicotine base products, the nicotine base form concentration in mg/mL for nicotine salt products, the equivalent nicotine base form concentration in mg/mL. Warnings statements 'KEEP OUT OF REACH OF CHILDREN' 'Avoid contact with eyes' 'Avoid contact with skin' 	✓ Compliant
Child-resistant packaging	TGO 95 applies to any nicotine vaping products	✓ Compliant
Tamper-evident packaging (non-mandatory)	Code of practice for tamper-evident packaging of therapeutic goods	✓ Compliant
Active ingredients	Nicotine (whether in base and/or salt form(s)) is the only active ingredient allowed in unregistered nicotine vaping products - these products must not contain any other active ingredients (subsection 7(1) of TGO 110).	✓ Compliant
Actual vs labelled nicotine concentration/content	The actual nicotine base form, nicotine salt and/or equivalent base form concentration or content in the nicotine vaping product must be within 90-110% of that stated	✓ Compliant
Limits on nicotine concentration	 Unregistered vaping products must have: for nicotine base products, a base form concentration, for nicotine salt products, an equivalent base form concentration, of no more than 100 mg/mL (subsection 7(1) of TGO 110). 	✓ Compliant
Prohibited ingredients	The substances must not be added as ingredients in unregistered nicotine vaping products (subsection 7(3) and Schedule 1 to TGO 110). • Acetoin • Benzaldehyde • Cinnamaldehyde • Diacetyl • diethylene glycol • ethylene glycol • pentane-2,3-dione • vitamin E acetate	✓ Compliant
Microbiological standards	Unregistered nicotine vaping products are also automatically subject to the requirements under subsection 11(1) of the Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018	✓ Compliant