21/4/17

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Madam / Sir,

Thanking you for the opportunity to contribute.

As a small business / sole trader, **we do not support** the TGA recommendations with respect to invasive low risk class 1 medical devices.

You have classified invasive class 1 medical devices applied on the skin and used vaginally as very low risk. This is not correct, the risk is higher, as poor manufacturing practices and / or substandard ingredients could lead to significant community health issues, including infertility, sickness or death.

The impact of the poorly manufactured or substandard products would not be known at first use as you have mentioned in the document. It could take days, months or even years.

[redacted]

Astroglide Pty Ltd

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