

Regulation (EU) 2017/745 of the European Parliament & of the Council

This declaration applies to all products sold by tvONE.

All tvONE products are designed and manufactured in such a way as to reduce substances or particles from being released from the device.

All tvONE Products

- Are NOT invasive nor come into direct contact with the human body
- Do NOT (re)administer medicines, body liquids or other substances, including gases to/from the body
- Do NOT transport or store such medicines , body fluids or substances, including gases, to be (re)administered to the body

Therefore the list of prohibited substances referenced in Section 10.4.1 of the Regulation does not apply.

Signed:

David M Reynaga

David Reynaga Chief Technology Officer 12th September 2024