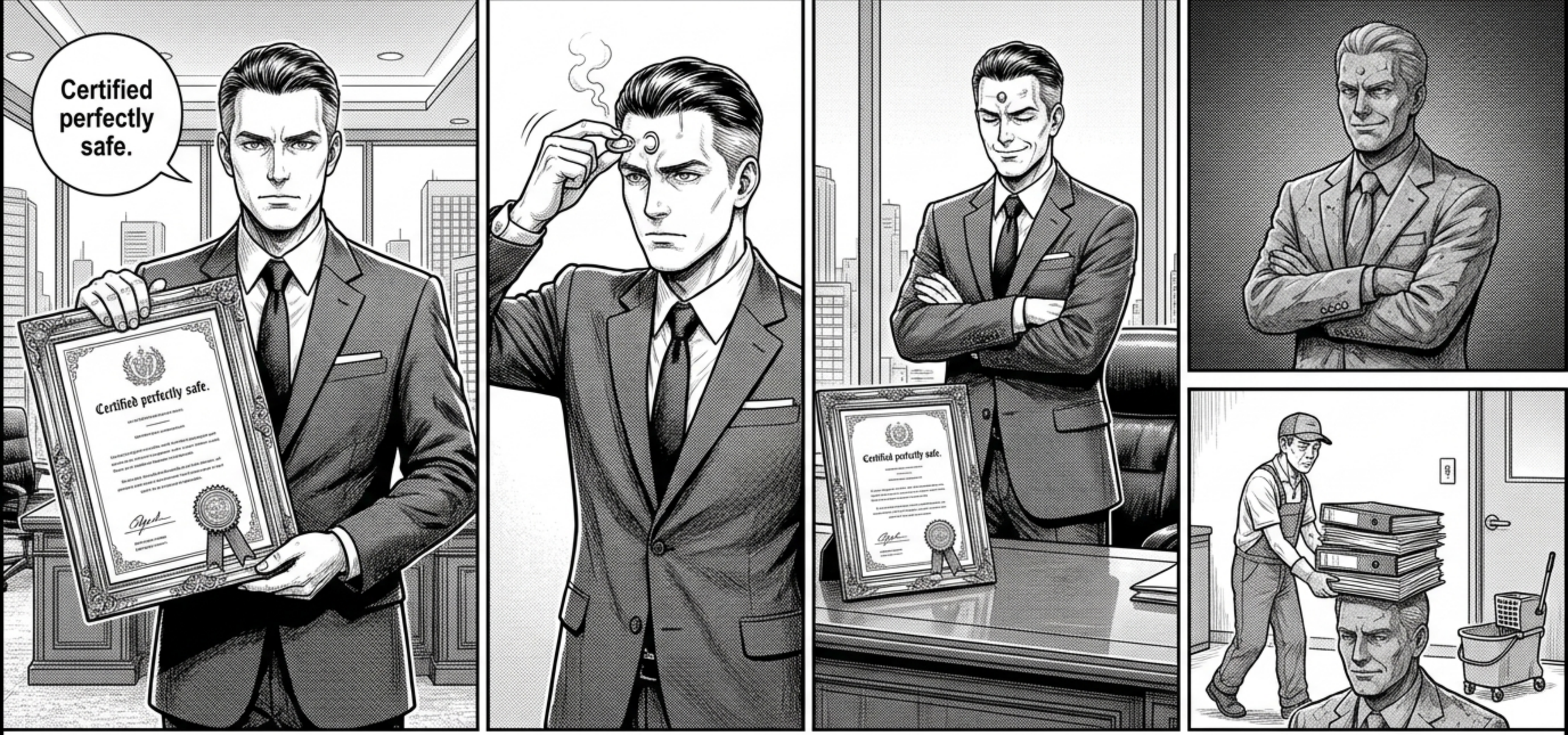

A basic biological reactivity certification does not guarantee a material is fundamentally suitable for continuous implantation.

Paperwork offers little physical protection.