

INTEGRA Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
FLAMEBOY	145000, 145003

comply with:


EU Regulations	Scope	Date effective
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007

EU Standards	Scope
EN 9001:2015	Quality Management

USA Regulations	Scope
17 CFR Parts 240 & 249b	Dodd frank “Conflict minerals”
27 CCR Parts 25102-27001	Proposition 65: The safe drinking water and toxic enforcement act

Zizers, February 19, 2021


Urs Hartmann
CEO


Thomas Neher
Quality Manager