Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
VACUSAFE	**158300, 158310, 158320**
Accessory	**158395**

comply with:

EU Provisions	**Scope**
2014/35/EU	Low voltage directive (LVD)
2014/30/EU	Electromagnetic compatibility (EMC)
2012/19/EU	Waste electrical and electronic equipment (WEEE)
2011/65/EU	Restriction of hazardous substances (RoHS)
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)
2019/1782	External power supply efficiency
EN 9001:2015	Quality Management
EN 61010-1:2019	Safety general laboratory equipment
EN 61326-1:2013	Electromagnetic compatibility laboratory equipment
EN 62368-1:2021	Safety information technology equipment

UK Provisions	**Scope**
S.I. 2016/1101	Electrical equipment safety
S.I. 2016/1091	Electromagnetic compatibility (EMC)
S.I. 2013/3113	Waste electrical and electronic equipment (WEEE)
S.I. 2012/3032	Restriction of hazardous substances (RoHS)
BS 61010-1:2010	Safety general laboratory equipment
BS 63000:2018	Restriction of hazardous substances (RoHS)

USA Provisions	Scope
47 CFR Part 15 (FCC)	Electromagnetic compatibility (EMC)
10 CFR Part 430	External power supply efficiency (CEC VI)
17 CFR Parts 240 & 249b	Dodd frank “Conflict minerals”
27 CCR Parts 25102-27001	Proposition 65: The safe drinking water and toxic enforcement act
TSCA 40 CFR Part 751	Toxic substances control act
UL 61010-1:2012	Safety general laboratory equipment

CAN Provisions	Scope
CSA-C22.2 No. 61010-1	Safety general laboratory equipment

CHN Provisions	Scope
AQSIQ Order 5 /2001	China compulsory certification mark (CCC) safety and EMC requirements for electrical equipment
Order 32/2016	Restriction of hazardous substances (RoHS)
GB4943.1-2011	Information technology equipment safety
GB9254-2008	Information technology equipment radio disturbance
GB17625.1-2012	EMC limits for harmonic current emissions
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)

JPN Provisions	Scope
PSE (Denan) Law	Electrical appliance and material safety law

KOR Provisions	
KC 61010-1	Safety general laboratory equipment
EN 61010-1:2019	Based on IEC 61010-1, safety general laboratory equipment

AUS/NZL Provisions	
AS/NZ 61010-1:2003	Safety general laboratory equipment
EN 61010-1:2019	Based on IEC 61010-1, safety general laboratory equipment

Zizers, 2026-07-27

Urs Hartmann
CEO

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Head of Corporate Quality