



Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
VACUSAFE	158300, 158310, 158320

comply with:

EU Directives	Scope	Date effective
2014/35/EU	Low voltage directive (LVD)	20.04.2016
2014/30/EU	Electromagnetic compatibility (EMC)	20.04.2016
2012/19/EC	Waste electrical and electronic equipment (WEEE)	14.02.2014
2011/65/EC	Restriction of hazardous substances (RoHS)	03.01.2013

EU Regulations	Scope	Date effective
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007
2019/1782	External power supply efficiency	01.04.2020

EU Standards	Scope
EN 9001:2015	Quality Management
EN 61010-1:2010	Safety general laboratory equipment
EN 61326-1:2013	Electromagnetic compatibility laboratory equipment

GBR Regulations	Scope	Date effective
S.I. 2016/1101	Electrical equipment safety	08.12.2016
S.I. 2016/1091	Electromagnetic compatibility (EMC)	08.12.2016
S.I. 2013/3113	Waste electrical and electronic equipment (WEEE)	01.01.2019
S.I. 2012/3032	Restriction of hazardous substances (RoHS)	02.01.2013

GBR Standards	Scope
BS 61010-1:2010	Safety general laboratory equipment
BS 63000:2018	Restriction of hazardous substances (RoHS)

VACUSAFE – Declaration of conformity

USA Regulations	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
USA Standards	Scope
UL 61010-1:2012	Safety general laboratory equipment

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


CHN Regulations	Scope	Date effective
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016
CHN Standards	Scope	
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)	

JPN Regulations	Scope	Date effective
PSE (Denan) Law	Electrical appliance and material safety law	01.01.2014

EAC Технический регламент Таможенного союза		
TP TC 004/2011	О безопасности низковольтного оборудования	
TP TC 020/2011	Электромагнитная совместимость технических средств	

Zizers, March 29, 2021


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