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 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 61010-1:2020	Safety general laboratory equipment	
EN 61326-1:2013	Electromagnetic compatibility laboratory equipment	
EN 60950-1:2013	Safety information technology equipment	
EN 62368-1:2021	Safety information technology 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)	

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
TSCA 40 CFR Part 751	Toxic substances control 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
AQSIQ Order 5 /2001	China compulsory certification mark (CCC) safety and EMC requirements for electrical equipment	01.08.2003
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016
CHN Standards	**Scope**	
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 Regulations	Scope	Date effective
PSE (Denan) Law	Electrical appliance and material safety law	01.01.2014

KOR Regulations	
KC 61010-1	Safety general laboratory equipment
KC 62368	Safety information technology equipment

AUS/NZL Regulations	
AS/NZ 61010-1:2003	Safety general laboratory equipment
AS/NZ 62368-1:2022	Safety information technology equipment

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

Zizers, October 4, 2023

Urs Hartmann
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