



## Declaration of conformity

**INTEGRA Biosciences AG – 7205 Zizers, Switzerland**

declares on its own responsibility that the devices

Description	Models
<b>VACUSAFE</b>	<b>158300, 158310, 158320</b>

comply with:

<b>EU Directives</b>	<b>Scope</b>	<b>Date effective</b>
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

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

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

<b>GBR Regulations</b>	<b>Scope</b>	<b>Date effective</b>
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

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

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<b>USA Regulations</b>	<b>Scope</b>
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
<b>USA Standards</b>	<b>Scope</b>
UL 61010-1:2012	Safety general laboratory equipment

<b>CAN Standards</b>	<b>Scope</b>
CSA-C22.2 No. 61010-1	Safety general laboratory equipment

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

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

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

Zizers, March 29, 2021

  
Urs Hartmann  
CEO

  
Thomas Neher  
Quality Manager