Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
PIPETBOY acu 2	**155000, 155015, 155016, 155017, 155018, 155019, 155022, 155023, 155024**
Accessories	**153210, 153211, 153214, 153216, 155066**

comply with:

International	**Scope**
UN 38.3	Lithium battery testing requirements

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
2006/66/EC	Battery directive	26.09.2008
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
1103/2010	Capacity labelling of portable batteries	30.11.2010
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	
EN 62133-2:2017	Batteries containing non-acid electrolytes	

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. 2008/2164	Batteries and accumulators regulations	26.09.2008
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 62368-1:2020	Safety information technology equipment	
BS 63000:2018	Restriction of hazardous substances (RoHS)	

USA Regulations	Scope	Date effective
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	
20 CCR Parts 1601-1608	CEC BCS, Battery charging efficiency	01.01.2017
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	(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	
GB31241-2014	Safety for Lithium-ion batteries	
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, 2023-12-08

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