



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
VIAFLO Pipettes	4011, 4012, 4013, 4014, 4015, 4016, 4621, 4622, 4623, 4624, 4626, 4631, 4632, 4633, 4634, 4636, 4641, 4642, 4646
VOYAGER Pipettes	4721, 4722, 4723, 4724, 4726, 4731, 4732, 4736, 4743, 4744, 4763, 4764
D-ONE Module	4531, 4532
Accessories	3214, 3215, 3216, 3217, 3218, 4200, 4205, 4210, 4211, 4215, 4221, 4226

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
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	

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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	
TSCA 40 CFR Part 751	Toxic substances control act	
20 CCR Parts 1601-1608	CEC BCS, Battery charging efficiency	01.01.2017

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

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

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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
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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

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

International Standards	
ISO 8655-2	Piston pipettes

Zizers, March 27, 2023


Urs Hartmann
CEO


Daniel Bächli
Head of Corporate Quality