



Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the device

Description	Model
ASSIST	4500
Accessory	127907

complies 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
2014/53/EU	Radio equipment directive (RED)	13.06.2016
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 61010-2-081:2020	Safety automatic 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. 2017/1206	Radio equipment (RED)	26.12.2017
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 61010-2-081:2020	Safety automatic laboratory equipment	
BS 63000:2018	Restriction of hazardous substances (RoHS)	

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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	
UL 61010-2-081:2019	Safety automatic laboratory equipment	
CAN Standards	Scope	
CSA-C22.2 No. 61010-1	Safety general laboratory equipment	
CSA C22.2 No. 61010-2-081	Safety automatic 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

ЕАС Технический регламент Таможенного союза

TP TC 004/2011 О безопасности низковольтного оборудования

TP TC 020/2011 Электромагнитная совместимость технических средств

Zizers, April 11, 2022


Urs Hartmann
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