



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland
declares on its own responsibility that the device

Description	Model
ASSIST PLUS	4505
Accessory	128909, 4548, 4549, 4900, 4901, 4950

complies with:

EU Provisions	Scope
2014/35/EU	Low voltage directive (LVD)
2014/30/EU	Electromagnetic compatibility (EMC)
2014/53/EU	Radio equipment directive (RED)
2012/19/EC	Waste electrical and electronic equipment (WEEE)
2011/65/EC	Restriction of hazardous substances (RoHS)
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)
2019/1782	External power supply efficiency
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

UK Provisions	Scope
S.I. 2016/1101	Electrical equipment safety
S.I. 2016/1091	Electromagnetic compatibility (EMC)
S.I. 2017/1206	Radio equipment (RED)
S.I. 2013/3113	Waste electrical and electronic equipment (WEEE)
S.I. 2012/3032	Restriction of hazardous substances (RoHS)
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)

ASSIST PLUS – Declaration of conformity

USA Provisions	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
UL 61010-1:2012	Safety general laboratory equipment
UL 61010-2-081:2019	Safety automatic laboratory equipment

CAN Provisions	Scope
CSA-C22.2 No. 61010-1	Safety general laboratory equipment
CSA C22.2 No. 61010-2-081	Safety automatic laboratory equipment

CHN Provisions	Scope
AQSIQ Order 5 /2001	China compulsory certification mark (CCC) safety and EMC requirements for electrical equipment
Order 32/2016	Restriction of hazardous substances (RoHS)
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 Provisions	Scope
PSE (Denan) Law	Electrical appliance and material safety law

ЕАС Технический регламент Таможенного союза

TP TC 004/2011	О безопасности низковольтного оборудования
TP TC 020/2011	Электромагнитная совместимость технических средств

Zizers, 2025-09-29



Urs Hartmann
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