



Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the device

Description	Model
ASSIST	4500
Power supply	127907

complies with:

EU Provisions	Scope
2014/30/EU	Electromagnetic compatibility (EMC)
2014/35/EU	Low voltage directive (LVD)
2014/53/EU	Radio equipment directive (RED)
2012/19/EU	Waste electrical and electronic equipment (WEEE)
2011/65/EU	Restriction of hazardous substances (RoHS)
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)
2019/1021	Regulation on persistent organic pollutants (POP)
2019/1782	External power supply efficiency
EN 61326-1:2013	Electromagnetic compatibility laboratory equipment
EN 61010-2-081:2020	Safety automatic laboratory equipment
EN 62368-1:2021	Safety information technology equipment
EN 61010-1:2019	Safety general laboratory 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	Documentation restriction of hazardous substances (RoHS)

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
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
CAN/CSA-C22.2 No. 61010-1: 2018	Safety general laboratory equipment
CAN/CSA C22.2 No. 61010-2-081:2019	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

ASSIST – Declaration of conformity

KOR Provisions	Scope
IEC 61010-1	Safety general laboratory equipment
IEC 61010-2-81	Safety automatic and semiautomatic laboratory equipment
KS C 9610-4-2	ESD immunity
KS C 9610-4-3	Radiated RF immunity
KS C 9610-4-4	EFT immunity
KS C 9610-4-5	Surge immunity
KS C 9610-4-6	Conducted RF immunity
KS C 9610-4-11	Voltage dips immunity
KS C 9811:2019	Emission ISM equipment

ANZAC Provisions

IEC 61010-1	Safety general laboratory equipment
IEC 61010-2-081	Safety automatic laboratory equipment
IEC 61326-1	Electromagnetic compatibility laboratory equipment

Zizers, 2026-07-27



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