



## Declaration of Conformity

**INTEGRA Biosciences AG – 7205 Zizers, Switzerland**

declares on its own responsibility that the device

Description	Model
<b>ASSIST PLUS</b>	<b>4505</b>
<b>Accessory</b>	<b>128909, 4548, 4549</b>

complies with:

<b>EU Directives</b>	<b>Scope</b>	<b>Date effective</b>
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
<b>EU Regulations</b>	<b>Scope</b>	<b>Date effective</b>
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007
2019/1782	External power supply efficiency	01.04.2020
<b>EU Standards</b>	<b>Scope</b>	
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	
<b>GBR Regulations</b>	<b>Scope</b>	<b>Date effective</b>
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
<b>GBR Standards</b>	<b>Scope</b>	
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

---

<b>USA Regulations</b>	<b>Scope</b>	
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	
<b>USA Standards</b>	<b>Scope</b>	
UL 61010-1:2012	Safety general laboratory equipment	
UL 61010-2-081:2019	Safety automatic laboratory equipment	
<b>CAN Standards</b>	<b>Scope</b>	
CSA-C22.2 No. 61010-1	Safety general laboratory equipment	
CSA C22.2 No. 61010-2-081	Safety automatic laboratory equipment	
<b>CHN Regulations</b>	<b>Scope</b>	<b>Date effective</b>
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
<b>CHN Standards</b>	<b>Scope</b>	
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)	
<b>JPN Regulations</b>	<b>Scope</b>	<b>Date effective</b>
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 17, 2023



Urs Hartmann  
CEO



Daniel Bächli  
Head of Corporate Quality