



Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland


declares on its own responsibility that the **ASSIST PLUS** (Model 4505) complies with:

| EU Standards | Scope | |
|------------------------|------------------------------------------------------------------------------|-----------------------|
| EN 9001:2015 | Quality Management | |
| EN 61010-1:2010 | Safety general laboratory equipment | |
| EN 61326-1:2013 | Electromagnetic compatibility laboratory equipment | |
| EN 61010-2-081:2015 | Safety automatic laboratory equipment | |
| 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 (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 |
| GBR Standards | Scope | |
| EN 61010-1:2010 | Safety general laboratory equipment | |
| EN 61010-2-081:2015 | Safety automatic laboratory equipment | |
| EN 63000:2018 | Restriction of hazardous substances (RoHS) | |
| 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 |

| USA Standards | Scope | |
|---------------------------|-------------------------------------------------------------------|-----------------------|
| UL 61010-1:2012 | Safety general laboratory equipment | |
| UL 61010-2-081:2015 | Safety automatic laboratory equipment | |
| USA Regulations | Scope | |
| 47 CFR Part 15 (FCC) | Electromagnetic compatibility (EMC) | |
| 17 CFR Parts 240 & 249b | Dodd frank "Conflict minerals" | |
| 27 CCR Parts 25102-27001 | Proposition 65: The safe drinking water and toxic enforcement act | |
| 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 Standards | Scope | |
| SJ/T 11364-2014 | Restriction of hazardous substances (RoHS) | |
| CHN Regulations | Scope | Date effective |
| Order 32/2016 | Restriction of hazardous substances (RoHS) | 01.07.2016 |
| JPN Regulations | Link | Date effective |
| PSE (Denan) Law | Electrical appliance and material safety law | 01.01.2014 |

Zizers, January 14, 2021


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