



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

| Description | Models |
|----------------------|-------------------|
| MAG/HEATMAG | 4900, 4901 |
| Mains adapter | 137710 |

comply 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 |
| 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 |
| 2019/1021 | Regulation on persistent organic pollutants | 20.06.2019 |
| 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 61010-2-010:2020 | Safety heating devices |
| EN 60950-1:2013 | Safety information technology equipment |
| EN 62368-1:2021 | Safety information technology equipment |
| EN 50364:2019 | Human exposure to electromagnetic fields |

| 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. 2013/3113 | Waste electrical and electronic equipment (WEEE) | 01.01.2019 |
| S.I. 2012/3032 | Restriction of hazardous substances (RoHS) | 02.01.2013 |

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| GBR Standards | Scope |
|----------------------|--|
| BS 61010-1:2010 | Safety general laboratory equipment |
| BS 62368-1:2020 | Safety information technology equipment |
| BS 63000:2018 | Restriction of hazardous substances (RoHS) |

| USA Regulations | Scope | Date effective |
|--------------------------|---|-----------------------|
| 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 61010-2:2019 | Safety heating devices |

| CAN Standards | Scope |
|-----------------------------|-------------------------------------|
| CSA-C22.2 No. 61010-1 | Safety general laboratory equipment |
| CSA-C22.2 No. 61010-2-10 | Safety heating devices |

| CHN Regulations | Scope | Date effective |
|------------------------|--|-----------------------|
| AQSIQ Order 5 /2001 | (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) |

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| JPN Regulations | Scope | Date effective |
|------------------------|--|-----------------------|
| PSE (Denan) Law | Electrical appliance and material safety law | 01.01.2014 |
| JIS C1010-1:2019 | Safety general laboratory equipment | |

| KOR Regulations | Scope | Date effective |
|------------------------|---|-----------------------|
| KC 61010-1 | Safety general laboratory equipment | |
| KC 61010-2-010 | Safety heating devices | |
| KC 62368 | Safety information technology equipment | |

| ANZAC Regulations | Scope | Date effective |
|--------------------------|---|-----------------------|
| AS 61010-1:2003 | Safety general laboratory equipment | |
| IEC 61010-2-010:2019 | Safety heating devices | |
| AS/NZS 62368.1:2022 | Safety information technology equipment | |

Zizers, 2023-12-08


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