



Declaration of conformity

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

| Description | Model |
|------------------------------|-------------|
| VIAFILL Dispenser | 5600 |
| VIAFILL Plate Stacker | 5910 |

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 |

| 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 |

| 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 |

| 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) |

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| 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 |

| USA Standards | Scope |
|----------------------|---------------------------------------|
| UL 61010-1:2012 | Safety general laboratory equipment |
| UL 61010-2-081:2015 | Safety automatic laboratory equipment |

| 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 Regulations | Scope | Date effective |
|------------------------|--|-----------------------|
| Order 32/2016 | Restriction of hazardous substances (RoHS) | 01.07.2016 |


| CHN Standards | Scope |
|----------------------|--|
| SJ/T 11364-2014 | Restriction of hazardous substances (RoHS) |

| JPN Regulations | Link | Date effective |
|------------------------|--|-----------------------|
| PSE (Denan) Law | Electrical appliance and material safety law | 01.01.2014 |

| EAC Технический регламент Таможенного союза | |
|--|--|
| TP TC 004/2011 | О безопасности низковольтного оборудования |
| TP TC 020/2011 | Электромагнитная совместимость технических средств |

Zizers, March 29, 2021


Urs Hartmann
CEO


Thomas Neher
Quality Manager