



# Declaration of conformity

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

declares on its own responsibility that the device

| Description          | Model       |
|----------------------|-------------|
| <b>VIAFLO ASSIST</b> | <b>4500</b> |

complies with:

| <b>EU Directives</b> (DoW: Date of Withdrawal) | Before DoW         | DoW        | After DoW         |
|--|--------------------|------------|-------------------|
| Low Voltage Equipment                          | <b>2006/95/EC</b>  | 20.04.2016 | <b>2014/35/EU</b> |
| Electromagnetic Compatibility                  | <b>2004/108/EC</b> | 20.04.2016 | <b>2014/30/EU</b> |
| Restriction of Hazardous Substances            | <b>2011/65/EU</b>  |            |                   |
| Waste Electrical and Electronic Equipment      | <b>2012/19/EU</b>  |            |                   |
| Radio Equipment Directive                      | <b>1999/5/EC</b>   | 13.06.2016 | <b>2014/53/EU</b> |

## EU Regulations

|  |                  |
|--|------------------|
| Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) | <b>1907/2006</b> |
| Ecodesign - Power supplies   | <b>278/2009</b>  |

## Standards for EU


|  |                            |
|--|----------------------------|
| Safety requirements for electrical equipment for measurement, control and laboratory use - General requirements. | <b>EN 61010-1: 2010</b>    |
| Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.   | <b>EN 61010-2-81: 2015</b> |
| Electrical equipment for measurement, control and laboratory use - EMC requirements.                             | <b>EN 61326-1: 2013</b>    |

## Standards for Canada and USA

|   |  |
|---|--|
| Safety requirements for electrical equipment for measurement, control and laboratory use - General requirements.  | <b>CAN/CSA-C22.2 No. 61010-1</b>                                 |
| Safety requirements for electrical equipment for measurement, control and laboratory use - General requirements.  | <b>UL 61010-1</b>  |
| Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.  | <b>UL 61010-2-81</b>   |
| Operation is subject to the following two conditions:<br>(1) this device may not cause harmful interference, and<br>(2) this device must accept any interference received, including interference that may cause undesired operation. | <b>Part 15 of the FCC Rules<br/>Contains FCC ID:<br/>PI4410B</b> |

Zizers, June 19, 2017

  
 Elmar Morscher  
 CEO

  
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 Quality Manager