



## Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
<b>WELLJET Dispenser</b>	<b>5000</b>
<b>WELLJET Dispenser Stacker</b>	<b>5001</b>
<b>Accessory</b>	<b>128909</b>

comply 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/EU	Waste electrical and electronic equipment (WEEE)	14.02.2014
2011/65/EU	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
<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 62368-1:2021	Safety information technology equipment	
EN 301 489-1 V2.2.3	EMC radio equipment: technical requirements	
EN 301 489-3 V2.2.0	EMC radio equipment: conditions for operating	
EN 300 330 V2.1.1	Short range devices	
EN 50364:2019	Human exposure to electromagnetic fields	

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<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 62368-1:2020	Safety information technology equipment
BS 63000:2018	Restriction of hazardous substances (RoHS)

<b>USA Regulations</b>	<b>Scope</b>
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
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>
CAN/CSA-C22.2 No. 61010-1	Safety general laboratory equipment
CAN/CSA C22.2 No. 61010-2-81	Safety automatic laboratory equipment

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<b>CHN Regulations</b>	<b>Scope</b>	<b>Date effective</b>
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016

<b>CHN Standards</b>	<b>Scope</b>
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

### **EAC Технический регламент Таможенного союза**

TP TC 004/2011	О безопасности низковольтного оборудования
TP TC 020/2011	Электромагнитная совместимость технических средств

### **KOR Regulations**


KC 61010-1	Safety general laboratory equipment
KC 61010-2-081	Safety automatic laboratory equipment
KC 62368-1	Safety information technology equipment

### **AUS/NZL Regulations**

AS/NZ 61010-1:2003	Safety general laboratory equipment
IEC 61010-2-081:2019	Safety automatic laboratory equipment
AS/NZ 62368-1:2022	Safety information technology equipment

Zizers, 2023-12-08

  
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