



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
WELLJET Dispenser	5000
WELLJET Dispenser Stacker	5001
Accessory	128909

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
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
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 61010-1:2020	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	

WELLJET – Declaration of conformity

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

GBR Standards	Scope
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)

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
TSCA 40 CFR Part 751	Toxic substances control act

USA Standards	Scope
UL 61010-1:2012	Safety general laboratory equipment
UL 61010-2-081:2019	Safety automatic laboratory equipment

CAN Standards	Scope
CAN/CSA-C22.2 No. 61010-1	Safety general laboratory equipment
CAN/CSA C22.2 No. 61010-2-81	Safety automatic laboratory equipment

WELLJET – Declaration of conformity

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	Scope	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

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, August 4, 2023


Urs Hartmann
CEO


Daniel Bächli
Head of Corporate Quality