



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
MEDIAJET	103005, 103006
MEDIAJET vario	113000, 113001, 113002

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/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 61010-1:2010	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	
BS 61010-1:2010	Safety general laboratory equipment	
BS 61010-2-081:2020	Safety laboratory 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 61010-2-081:2015	Safety automatic laboratory equipment

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

Zizers, 2023-12-08


 Urs Hartmann
 CEO


 Daniela Gross
 Head of Corporate Quality