



## Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
<b>MEDIAJET</b>	<b>103005, 103006</b>
<b>MEDIAJET vario</b>	<b>113000, 113001, 113002</b>

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 61010-2-081:2015	Safety laboratory equipment	
BS 63000:2018	Restriction of hazardous substances (RoHS)	

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<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	
<b>USA Standards</b>	<b>Scope</b>	
UL 61010-1:2012	Safety general laboratory equipment	
UL 61010-2-081:2015	Safety automatic laboratory equipment	
<b>CAN Standards</b>	<b>Scope</b>	
CSA-C22.2 No. 61010-1	Safety general laboratory equipment	
CSA-C22.2 No. 61010-2-81	Safety automatic laboratory equipment	
<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)	

Zizers, November 25, 2022

  
Urs Hartmann  
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