



Declaration of Conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
MEDIACLAVE 10	136 000, 136 005, 136 010, 136 015, 136 020, 136 025
MEDIACLAVE 30	136 050, 136 055

comply with:

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 61010-2-010:2017	Safety Heating Devices	
EN 9606-1:2018	Qualification test of welders - Fusion welding - Part 1: Steels	
EN 15614-1:2017	Specification and qualification of welding procedures	
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
2014/68/EU	Pressure equipment (PED)	19.06.2016

Description of pressure vessels

Operational fluid	liquids/gases	Allowable temperature TS	0-126 °C
Fluid group	2	Test pressure PT	2.5 bar
Max operating pressure	1.4 bar	Pressure test medium	water
Safety valve set pressure,		Marking	CE1253
Max allowable pressure PS	1.7 bar	Safety equipment	assembly
MEDIACLAVE 10:		MEDIACLAVE 30:	
Serial No.	0267-7999	Serial No.	8000-18000
Category (2014/68/EU)	I (Art. 13)	Category (2014/68/EU)	II (Art. 13)
Chamber volume V	16.3 l	Chamber volume V	43.2 l
Drawing No./Rev	136400/09	Drawing No./Rev	136450/09

Description of assembly	Pressure vessel, circulation pump, safety valve, circulation heater, heat exchanger, piping
Conformity assessment procedure	Module: A2 (2014/68/EU)
Certificate No.	PED-Z-COS.EP.5507079
Notified body for inspection	Swiss Safety Center AG, CH-8304 Wallisellen, CE1253
Certified Q-System ISO 9001:2015	SQS, CH-3052 Zollikofen, Reg. No. 15072

EU Regulations	Scope	Date effective
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007

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GBR Standards	Scope	
BS 61010-1:2010	Safety general laboratory equipment	
BS 61010-2-010:2020	Safety equipment for the heating of materials	
BS 63000:2018	Restriction of hazardous substances (RoHS)	
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. 2016/1105	Pressure equipment safety	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


USA Standards	Scope	
UL 61010-1:2012	Safety general laboratory equipment	
UL 61010-2-010:2015	Safety heating devices	
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	

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

CHN Standards	Scope	
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)	
CHN Regulations	Scope	Date effective
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016

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