



# Declaration of Conformity

**INTEGRA Biosciences AG – 7205 Zizers, Switzerland**

declares on its own responsibility that the devices

Description	Models
<b>MEDIACLAVE 10</b>	<b>136 000, 136 005, 136 010, 136 015, 136 020, 136 025</b>
<b>MEDIACLAVE 30</b>	<b>136 050, 136 055</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
2014/68/EU	Pressure equipment directive (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, Max allowable pressure PS	1.7 bar	Marking	CE1253
		Safety equipment	assembly

### MEDIACLAVE 10:

Serial No.	0267-7999
Category (2014/68/EU)	I (Art. 13)
Chamber volume V	16.3 l
Drawing No./Rev	136400/09

### MEDIACLAVE 30:

Serial No.	8000-18000
Category (2014/68/EU)	II (Art. 13)
Chamber volume V	43.2 l
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

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


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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. 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
<b>GBR Standards</b>	<b>Scope</b>	
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)	
<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 61010-2-010:2015	Safety heating devices	
<b>CAN Standards</b>	<b>Scope</b>	
CSA-C22.2 No. 61010-1	Safety general 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

  
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