



## 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

<b>MEDIACLAVE 10:</b>		<b>MEDIACLAVE 30:</b>	
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

<b>Description of assembly</b>	Pressure vessel, circulation pump, safety valve, circulation heater, heat exchanger, piping
<b>Conformity assessment procedure</b>	Module: A2 (2014/68/EU)
<b>Certificate No.</b>	PED-Z-COS.EP.5507079
<b>Notified body for inspection</b>	Swiss Safety Center AG, CH-8304 Wallisellen, CE1253
<b>Certified Q-System ISO 9001:2015</b>	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, March 29, 2021

  
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