



Declaration of Conformity **MEDIACLAVE 10**

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

comply with:

EU Directives (DoW: Date of Withdrawal)	Before DoW	DoW	After DoW
Low Voltage Equipment	2006/95/EC	20.04.2016	2014/35/EU
Pressure Equipment	97/23/EC	19.07.2016	2014/68/EU
Electromagnetic Compatibility	2004/108/EC	20.04.2016	2014/30/EU
Restriction of Hazardous Substances	2011/65/EU		
Waste Electrical and Electronic Equipment	2012/19/EU		

EU Regulation

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) **1907/2006**

Directive 97/23 EC and 2014/68/EU

Description of pressure vessel		Allowable temperature TS	0-126 °C
Operational fluid	liquids/gases	Volume	V 16.3 l
Fluid group	2	Test pressure	PT 2.5 bar
Category (97/23 EC)	I (Art. 9)	Pressure test medium	water
Category (2014/68/EU)	II (Art. 13)	Serial No.	0267-7999
Max operating pressure	1.4 bar	Marking	CE1253
Safety valve set pressure,	1.7 bar	Safety equipment	assembly
Max allowable pressure PS		Drawing No./Rev	136400/09

Description of assembly pressure vessel, circulation pump, safety valve, circulation heater, heat exchanger, piping

Conformity assessment procedure Module: A1 (97/23/EC) / 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 9001:2000 SQS, CH-3052 Zollikofen, Reg. No. 15072

Standards for EU

Safety requirements for electrical equipment for laboratory use	EN 61010-1: 2010
Electrical equipment for laboratory use - EMC requirements	EN 61326-1: 2013
Pressure cookers	EN 12778: 2002
Qualification test of welders - Fusion welding - Part 1: Steels	EN 9606-1: 2013
Specification and qualification of welding procedures	EN 15614-1: 2004
Metallic products types of inspection documents, Type 3.1 certificate	EN 10204: 2004
Safety devices for protection against excessive pressure	EN 4126-1: 2013

Standards for Canada and USA:

Safety requirements for electrical equipment for measurement, control and laboratory use **UL 61010-1**

Requirements for laboratory equipment for the heating of materials **UL 61010-2-10**

Pressure cookers **UL 136**

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. **Part 15 of the FCC Rules Class A**

Zizers, December 3, 2018

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CEO

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