



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

Low Voltage Equipment	2014/35/EU
Pressure Equipment	2014/68/EU
Electromagnetic Compatibility	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 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: 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

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 ISO 9606-1: 2018
Specification and qualification of welding procedures	EN ISO 15614-1: 2017
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, January 9, 2020


 Urs Hartmann
 CEO


 Thomas Neher
 Quality Manager