



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 Provisions	Scope
2014/35/EU	Low voltage directive (LVD)
2014/30/EU	Electromagnetic compatibility (EMC)
2012/19/EU	Waste electrical and electronic equipment (WEEE)
2011/65/EU	Restriction of hazardous substances (RoHS)
2014/68/EU	Pressure equipment directive (PED)

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
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Conformity assessment procedure	Module: A2 (2014/68/EU)
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Certificate No.	PED-Z-COS.EP.5507079
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Notified body for inspection	Swiss Safety Center AG, CH-8304 Wallisellen, CE1253
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Certified Q-System ISO 9001:2015	SQS, CH-3052 Zollikofen, Reg. No. 15072
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EU Provisions	Scope
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)
EN 9001:2015	Quality management
EN 61010-1:2020	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

UK Provisions	Scope
S.I. 2016/1101	Electrical equipment safety
S.I. 2016/1091	Electromagnetic compatibility (EMC)
S.I. 2016/1105	Pressure equipment safety
S.I. 2013/3113	Waste electrical and electronic equipment (WEEE)
S.I. 2012/3032	Restriction of hazardous substances (RoHS)
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)

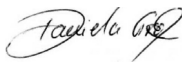
USA Provisions	Scope
47 CFR Part 15 (FCC)	Electromagnetic compatibility (EMC)
17 CFR Parts 240 & 249b	Dodd frank "Conflict minerals"
27 CCR Parts 25102-27001	Proposition 65: The safe drinking water and toxic enforcement act
TSCA 40 CFR Part 751	Toxic substances control act
UL 61010-1:2012	Safety general laboratory equipment
UL 61010-2-010:2019	Safety heating devices

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

CHN Provisions	Scope
Order 32/2016	Restriction of hazardous substances (RoHS)
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)

Zizers, 2025-11-28


 Urs Hartmann
 CEO


 Daniela Gross
 Head of Corporate
 Quality