Declaration of Conformity MEDIACLAVE 10
INTEGRA Biosciences AG – 7205 Zizers, Switzerland
declares on its own responsibility that the devices
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
Operational fluid liquids/gases  Allowable temperature TS 0-126 °C
Fluid group 2  Volume V 16.3 l
Category (97/23 EC) I (Art. 9)  Test pressure PT 2.5 bar
Category (2014/68/EU) II (Art. 13) Pressure test medium water
Max operating pressure 1.4 bar Serial No. 0267-7999
Max allowable pressure PS 1.7 bar Marking CE1253
Safety valve set pressure, Safety equipment assembly
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