



Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the device

Description Model

ASSIST 4500

complies 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
------------	-------------------------------------	------------

2014/53/EU	Radio equipment directive (RED)	13.06.2016
------------	---------------------------------	------------

2012/19/EC	Waste electrical and electronic equipment (WEEE)	14.02.2014
------------	--	------------

2011/65/EC	Restriction of hazardous substances (RoHS)	03.01.2013
------------	--	------------

EU Regulations	Scope	Date effective
-----------------------	--------------	-----------------------

1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007
-----------	--	------------

2019/1782	External power supply efficiency	01.04.2020
-----------	----------------------------------	------------

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 61010-2-081:2015	Safety automatic laboratory equipment
---------------------	---------------------------------------

GBR Regulations	Scope	Date effective
------------------------	--------------	-----------------------

S.I. 2016/1101	Electrical equipment safety	08.12.2016
----------------	-----------------------------	------------

S.I. 2016/1091	Electromagnetic compatibility (EMC)	08.12.2016
----------------	-------------------------------------	------------

S.I. 2017/1206	Radio equipment (RED)	26.12.2017
----------------	-----------------------	------------

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
----------------	--	------------

GBR Standards	Scope
----------------------	--------------

BS 61010-1:2010	Safety general laboratory equipment
-----------------	-------------------------------------

BS 61010-2-081:2015	Safety automatic laboratory equipment
---------------------	---------------------------------------

BS 63000:2018	Restriction of hazardous substances (RoHS)
---------------	--

ASSIST – Declaration of conformity

USA Regulations	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

USA Standards	Scope
UL 61010-1:2012	Safety general laboratory equipment
UL 61010-2-081:2015	Safety automatic laboratory equipment

CAN Standards	Scope
CSA-C22.2 No. 61010-1	Safety general laboratory equipment
CSA C22.2 No. 61010-2-081	Safety automatic laboratory equipment

CHN Regulations	Scope	Date effective
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016


CHN Standards	Scope
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)

JPN Regulations	Scope	Date effective
PSE (Denan) Law	Electrical appliance and material safety law	01.01.2014

EAC Технический регламент Таможенного союза	
TP TC 004/2011	О безопасности низковольтного оборудования
TP TC 020/2011	Электромагнитная совместимость технических средств

Zizers, March 29, 2021


Urs Hartmann
CEO


Thomas Neher
Quality Manager