

Declaration of Conformity

Manufacturer: BTX Molecular Delivery Systems¹
Address: 84 October Hill Road, Holliston, Massachusetts 01746, USA

We herewith declare that the following products:

Product Name(s):	Electroporation Systems	Electrofusion System
Models:	Gemini X2 (45-2041), Gemini SC (45-2043) ECM 830 (45-0662), ECM 630 (45-0652)	ECM 2001+ (45-2049) ECM 2001 LITE (45-2069)

Are in conformity of the following applicable European regulations and directives:

2014/35/EU	Low Voltage directive (LVD)
2014/30/EU	Electromagnetic Compatibility directive (EMC)
2011/65/EU	Restriction on the use of certain hazardous substances directive (RoHS) ²
2012/19/EU	Waste electrical and electronic equipment directive (WEEE) ³

Standards used to demonstrate conformity include:

EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use, General Requirements
EN 50581:2012	Assessment of products with respect to RoHS ²
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use –EMC requirements ³

Safety testing performed by Intertek Testing Services.

Listing Number 9801781

Test reports: 103169368 BOX-001,-002

Conforms to UL61010-1:2012

Certified to CSA C22.2#61010-1:2012



¹Harvard Bioscience hold an ISO 9001:2015 certificate BSI FM 629138 for its Quality Management System

²Classified as belonging to equipment categories 8 or 9

³Classified and tested as class B equipment in accordance with CISPR 11 definition in a basic electromagnetic environment. This equipment has also been tested and found to comply with the limits for a class A digital device, pursuant to CFR Title 47 part 15 of the FCC rules.

I, the undersigned, hereby declare that the equipment specified is in conformity with the relevant harmonised Union legislation. Signed for and on behalf of BTX at Holliston, USA



The Electroporation Experts

Signed:

A handwritten signature in black ink, appearing to read 'Mark Davis'.

Mark Davis

Harvard Bioscience, Director of Engineering

Date:

June 29, 2020