Declaration of Conformity

Manufacturer: BTX Molecular Delivery Systems
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 2001+ (45-2049), ECM 830 (45-0662), ECM 630 (45-0652)

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 RoHS²
- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use –EMC requirements³

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

Signed: Mark Davis
Date: April 26, 2018
Harvard Bioscience, Director of Engineering