We are attaching this “CERTIFICATE TO FOREIGN GOVERNMENT” from the Food and Drug Administration for your edification. This certificate allows MiMedx to export our allografts which are listed in the document.

This should be a clarifying explanation associated with questions related to the regulatory status of our amniotic membrane allografts that are processed in sheet form. Please note the statement in the last paragraph, “It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time.” This should clarify any questions related to the regulatory status of our allograft products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. CT:3CEY-ZRW7

Application Number: 1526-16

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

MiMedx Group, Inc., located at 1775 West Oak Commons Ct. NE, Marietta, GA 30062, USA, manufactured the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name	
AmbioDisk	Amniotic Membrane Allograft (sheet form)
Ambio2	Amniotic Membrane Allograft (sheet form)
Ambio5	Amniotic Membrane Allograft (sheet form)
AmnioFix	Amniotic Membrane Allograft (sheet form)
BioXclude	Amniotic Membrane Allograft (sheet form)
EpiBurn	Amniotic Membrane Allograft (sheet form)
EpiFix	Amniotic Membrane Allograft (sheet form)
EpiXL	Amniotic Membrane Allograft (sheet form)
Zitma Dry	Amniotic Membrane Allograft (sheet form)
AmbioDry2	Amniotic Membrane Allograft (sheet form)

The product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Public Health Service Act and regulations promulgated thereunder. The company listed above has certified to the FDA that the HCT/P meets the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time. The company listed above is subjected to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in compliance with the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271.

Signature_____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from December 04, 2015 to December 03, 2017.