Declaration of Conformity

Product Identification: See attached appendix for product names, catalog numbers, and other applicable identifiers etc.

Manufacturer:

Name:	ScyTek Laboratories, Inc.
Address:	205 South 600 West, Logan, Utah 84321
Country:	United States of America
Representative:	Emergo Europe

Authorized Representative:

Name:	Emergo Europe
Address:	Prinsessegracht 20, 2514 AP The Hague
Country:	The Netherlands
Tel:	(31) (0) 70 345-8570
Fax:	(31) (0) 70 345-7299

Classification and Conformity assessment route: ScyTek Laboratories, Inc. declares that the product listed is in conformity with the provisions of EU regulation IVDR 2017/746 for medical devices. ScyTek Laboratories, Inc. declares this product to be compliant as a Class A, non-sterile, qualitative device per the self-declaration conformity assessment route and classification rules laid out in ANNEX VIII or IVDR 2017/746. This declaration is supported by the Quality System approval to ISO 13485 issued by NQA, USA. All supporting documentation is retained at the premises of the manufacturer

Device Class: Class A, nonsterile

Device General Description: General chemical reagent used to provide a pathologist with adjunctive diagnostic information that may be incorporated into the pathologist's report, but that is not ordinarily reported to the clinician as an independent finding;

Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination;

See each products individual Instruction for Use (IFU) for exact descriptions, intended uses, and procedures.

Signature: 

Name: R. Michael Anderson

Place and Date: Logan, Utah 84321, USA
Jan. 2, 2019