



3506 Reedy Dr, Elkhart, IN 46514-0002 * (574)264-3440 * FAX (574)266-6222 * www.serim.com

Certified to ISO 9001:2015 and ISO 13485:2003

DECLARATION OF CONFORMITY

**Manufacturer's Name
and address:**

Serim Research Corporation
3506 Reedy Dr
Elkhart IN 46514
USA

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:

Serim Research Corporation
3506 Reedy Dr
Elkhart IN 46514
USA

Medical Devices:

Serim® Guardian™ HiSENSE Ultra 0.1™ Test Strips – Product Code 5167
Serim® Guardian™ Residual Chlorine Test Strips – Product Code 5100A
Serim® Residual Formaldehyde Test Strips - Product Code 5112
Serim® Guardian™ Residual Peroxide Test Strips – Product Code 5105
Serim® Guardian™ Peracetic Acid Test Strips – Product Code 5106
Serim® Guardian™ Bicarb pH II™ Test Strips – Product Code 5116A
Serim® Guardian™ Blood Leak Test Strips – Product Code 5119C
Serim® PeriScreen™ Test Strips – Product Code 5122

Water Quality tests:

Serim® Guardian™ Water Hardness Test Strips – Product Code 5129

Serim® Chlorine Control Pack – Product Code 5100QC

Risk Classification:

Product Code 5122 listed above is classified as a class 1 medical device in the United States.

Product Codes 5167, 5100A, 5112, 5105, 5106, 5116A, 5119C are classified as Class 2 medical devices in the United States

Product Codes 5129 and 5100QC are not considered as medical devices in the United States.

Quality Management System Certificate:

ISO 9001:2015 – Certificate number - FM 58237, issued – 03/12/2017, expires – 03/11/2020

ISO 13485:2003 – Certificate number - FM 95458, issued - 03/12/2017, expires – 02/28/2019

Standards Applied:

ISO 9001:2015

ISO 13485:2003

This declaration of conformity is valid from October 20, 2017

Authorised Signatory:

Robert C. Bozuelaski, PRESIDENT
Name, Position

10/20/17
Date

