

DECLARATION OF CONFORMITY

Name and Address of Product Owner:

SureScreen Diagnostics Limited of 1 Prime Parkway, Prime enterprise Park, Derby, DE1 3QB

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 Medical Devices IVD Directive 98/79/EC, and are CE marked accordingly in line with EU regulations.

Medical Device(s):

Urinalysis Reagent strips
Urine Drugs of Abuse tests and test systems
Oral fluid Drugs of Abuse tests and test systems
Alcostick Device and related consumables
Alcohol tests and test systems
FOB test devices
Infectious disease devices
COVID-19 test device
Pregnancy test devices
Ovulation test devices

Manufacturing Site:

SureScreen Diagnostics Limited, 1 Prime Parkway, Prime enterprise Park, Derby, DE1 3QB

Quality Management System Certificate:

ISO 9001:2015
ISO 13485:2016

Standards Applied:

In Vitro Diagnostic Device Directive (IVDD)

This declaration of conformity is valid from 21/02/2020 until 20/02/2021.

Authorised Signatory:



David Campbell

21/02/2020
Date