EC DECLARATION OF CONFORMITY

DoC No	: REG-01-F6
Manufacturer	: SureScreen Diagnostics LTD, Unit 1 Prime Parkway Prime Enterprise Park Derby DE1 3QB, UK
EC Representative	: SureScreen Ireland LTD, 9 Exchange Place L.F.S.C., Dublin 1 Ireland
Product Classification	: "General IVD"
Conformity Assessment Route	: Annex III IVDD(Directive 98/79/EC)
Product Name	: See Annexure
Description Of the device	: See Annexure
Standards Applied	: EN ISO 13485:2016, EN ISO 14971:2012 EN ISO 18113-1:2011, EN ISO 15223-1:2016 EN ISO 18113-4:2011, EN ISO 20417:2021 EN 13641:2002
GMDN Code	: 46994 Multiple drugs of abuse IVD, kit, immunochromatographic test (ICT), rapid

SureScreen Diagnostics

Statement:
I, the undersigned, hereby declare that the In-Vitro Diagnostic Device specified above and provided with CE marking, conform with the Essential Requirements of the EC Directive 98/79/EC In-Vitro Diagnostic Directive. This Declaration is supported by the EC Quality System Certificates according to the provision of relevant Annex(es) of above Directive.

D Campbell

David Campbell Date

Valid from signature date

Director
SureScreen Diagnostics Ltd
1 Prime Park Way
Prime Enterprise Park
Derby, DE1 3QB
United Kingdom

Annexure:

GMDN Code	Product Name	Description
46994	GINCUP10DS	10 Panel Integrated Drug Test (AMP/ BAR/ BZO/ COC/ MAMP/ MTD/ OPI/ PCP/ TCA/ THC)