

Monday, October 12, 2015

EC Declaration of Conformity
according to the Directive 98/79/EC
(applicable to Others/General IVD Devices only)

Product/s: Microscope slides
WR PN 89085-399 & 89085-398
Category: Others/General
Conformity assessment route: Annex III, except point 6, of Directive (Module A)
Applicable Standards: ISO8037/1-1986 (E) ISO8037-2 : 1997 (E)
EN ISO 15223-1-2012 EN 1041 : 2008
EN ISO14971:2012

The Manufacturer, herewith declares with sole responsibility that the above product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

The manufacturer hereby explicitly appoint :

Wellkang Ltd t/a Wellkang Tech Consulting located at 29 Harley Street, London W1G 9QR, UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Sincerely



Linda Shine
Quality Process Excellence Facilitator
Operations