Objective Imaging

Unit 1, Quy Court
Colliers Lane
Stow cum Quy
Cambridge CB25 9AU
Tel:+44 (0)1223 813777
Fax:+44 (0)1223 813778
www.objectiveimaging.com

Certification of Conformity with the European Parliament Directive 98/79/EC on In-Vitro Diagnostic Medical Devices

Objective Imaging Ltd hereby declare that they are the Manufacturer of a General Class IVD Whole Slide Imaging Scanner variously referred to as either "*Glissando*" or "*Desktop Scanner*".

For the purposes of identification a representative image of the scanner is shown below, together with some key functional characteristics.

Scans and produces digital images of up to 2 single standard sized glass slides (75mm x 25mm) or 1 double sized glass slide. Inbuilt high specification PC. Motorised XYZ axes. Objective magnification may be 20x or 40x. High Resolution digital camera.

In accordance with S.I. No. 304 of 2001 European Communities (In-Vitro Diagnostic Medical Devices) Regulations and Directive 98/79/EC we hereby confirm that the scanner meets the Essential Requirements set out in Annex I of the Directive, taking account of the intended purpose of the device. Our conformity assessment route (as detailed in Regulation 40, Article 9, of the Directive) has been fulfilment of the applicable obligations imposed by sections 1 to 5 of Annex III and we thus declare and ensure that the device meets the provisions of the Directive which apply.

The scanner is intended for in vitro diagnostic use as an aid to pathology professionals for creating, storing, and viewing digital Whole Slide Images (WSI) from formalin-fixed, paraffin-embedded tissue section preparations on 75 x 25 mm and 75 x 50 mm glass slides.

Objective Imaging Ltd has registered their intent to market and sell this scanner within the European Community with the Medicines and Healthcare products Regulatory Agency (MHRA).

This declaration of conformity is issued under the sole responsibility of Objective Imaging Ltd

Signed for and on behalf of Objective Imaging Ltd :

Date : 30 March 2016 At : Cambridge

Maurice Bowe
(Managing Director)