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Declaration of Conformity with EU Regulation 2017/746 of the European Parliament and of the Council of the European Union on In-Vitro Diagnostic Medical Devices

Notification of EU Authorised Representative

Objective Imaging Ltd hereby declare that they are the Manufacturer of a Class A IVD Whole Slide Imaging Scanner variously referred to as either "*Glissando*" or "*Objective Imaging 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 (75mm x 50mm) glass slide.

- Inbuilt control computer.
- Motorised XYZ axes.
- High resolution digital camera.
- 40X/0.75NA scanning objective lens.

In accordance with EU Regulation 2017/746, approved on 5 April 2017 by the European Parliament and of the Council of the European Union, we hereby confirm that the scanner meets the Essential Requirements set out in Annex I of the Regulation, taking account of the intended purpose of the device.

Objective Imaging initially validated and confirmed the functionality of the scanner described in November 2015. Since that time, several changes have been made both to key elements of hardware (the XYZ scanning stage) and software. The intended purpose of the scanner remains unchanged and these changes were fully validated and approved at the time.

The scanner is intended use for in vitro diagnostics as an aid to pathology professionals for creating, storing, and viewing digital Whole Slide Images (WSI) using a 40X objective lens 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 United Kingdom and the European Community with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Products Regulatory Authority (HPRA), Ireland. Following the UK's exit from the European Union, our EU Authorised Representative is declared to be as follows:

Acorn Regulatory Consultancy Services Ltd.
Knockmorris,
Cahir,
Co. Tipperary
E21 R766
Ireland

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

Signed for and on behalf of Objective Imaging Ltd:

Date: 14 January 2021

Lee Payne
(Technical Director)