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

Objective Imaging Ltd hereby declare that they are the Manufacturer of a Whole Slide Imaging Scanner variously referred to as either "*Glissando 20SL*" or *(Objective Imaging Auto-loading 20-slide Scanner"*.

The Glissando 20SL is a medium capacity scanner whose intended use within in vitro diagnostics is 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.

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 20 single standard sized glass slides (75mm x 25mm) or 10 double-sized (75mm x 50mm) glass slides.

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

In accordance with IVD Regulation (EU) 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.

This Declaration is supported by a Quality Management System approved to ISO13485:2016 standards (certification issued by BSI; Notified Body No: 0086). All supporting documents are retained at the premises of the Manufacturer.

Regulatory information is as follows:

- Basic UDI-DI Number: 506090585AAA001S3
- GTIN-13 Number: 5060905850037
- Objective Imaging SRN Number: GB-MF-000016742
- Product Code: A002HR20SL-40-OBJ
- SKU Code: GLISS-20SL-40X-IVD
- IVD Classification: Class A IVD. (As a Class A device Notified Body certification is not required)
- Eudamed EDMN Number: W0202050304

Objective Imaging Ltd has registered their intent to market and sell this scanner within the European Community with 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. (SRN No:IE-AR000000592)
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:

Lee Payne

Date: 13 May 2022

Signed by: Lee Payne

Issued at: Objective Imaging Ltd

Function: Technical Director