UK Declaration of Conformity

Dx365 GmbH,
Hedwig-Porschütz-Straße 14
10557
Berlin
GERMANY

declares that under our sole responsibility, the product:

Device Name: Igloo Reader Pro
Basic UDI-DI: 42624791800R-DAAN
UDI-DI: 4262479180034
Ref No: R-DA

is in conformity with all relevant Articles, Annexes, Essential Requirements, and provisions of the following UK Regulations, including all amendments and national legislation implementing these Regulations:

UK Medical Devices Regulation (2002) implementing the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Classification:

General IVD Medical Device – Agglutination Assay Digital Imaging Reader/Analyser IVD (GMDN Code 64179)

The following standards and technical specifications were applied:

EN ISO 14971:2019+A11:2021
ISO 15233-1: 2021
IEC 62304:2006+A1-2015
EN ISO 13485:2016+A11:2021

This product carries the UKCA mark, which was first affixed in January 2025. This product also carries the CE mark, first affixed in October 2024.

Signature

Date
28th January 2025

Beverley Scott
UK Responsible Person (UKRP)
(BCS Clinical Consulting Limited)
On behalf of Dx365 GmBH