

UK Declaration of Conformity

**Informatica Systems Limited
Aurora House Deltic Avenue
Rooksley
Milton Keynes
Buckinghamshire
MK13 8LW**

declares that under our sole responsibility, the product:

Skyline R1

is in conformity with the Essential Requirements and provisions of the following UK medical devices legislation:

UK Medical Devices Regulations (2002) The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (providing for the Medical Devices Directive 93/42/EEC)

Classification:

**Class 1 - Active Medical Device
Clinical Management Support Software (GMDN Code 61087)**

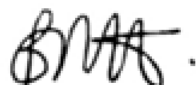
The following standards and technical specifications have been applied:

**BS EN ISO 13485:2016
BS EN 62304:2006 + A1:2015
BS EN ISO 14971:2012
BS EN ISO 15233-1:2016
DCB0129:2018**

This product carries the UKCA Mark, which was first affixed in August 2021.

Place
**Milton Keynes,
England**

Signature



Date
25th August 2021

**Beverley Scott
Person Responsible for Regulatory Compliance
(BCS Clinical Consulting Limited)
On behalf of Informatica Systems Limited**