

UKCA Declaration of Conformity



**School of Biomedical Engineering and Imaging Sciences within the Faculty of Life
Sciences and Medicine
King's College London
Strand
LONDON
WC2R 2LS
United Kingdom**

declares that under our sole responsibility, the product:

MIDI R1

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 Regulations (2002) (as they exist in 2026) via the Medical Devices Directive 93/42/EEC

Classification:

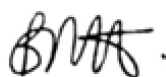
**Class I Software as a Medical Device
GMDN Code 44087 – Radiology Information System Application Software**

The following standards and technical specifications have been applied:

**BS EN ISO 13485:2016+A11-2021
BS EN IEC 62304:2006 + A1:2015
BS EN ISO 14971:2019+A11-2021
BS EN ISO 15233-1:2021
DCB0129:2018**

This product carries the UKCA Mark, which was first affixed in March 2026.

Signature

A handwritten signature in black ink, appearing to be "BMA".

Date

13th March 2026

Beverley Scott Person Responsible for Regulatory Compliance
On behalf of King's College London