

UKCA Declaration of Conformity



according to the UK Medical Devices Regulations 2002 (*UK SI 2002 No 618*, as amended)

Manufacturer: Three Palm Software

Address: 16 Yankee Point Drive, Carmel, CA 93923, USA

UK Responsible Person:

MIS Healthcare

26-27 Capital Park, London, NW9OEQ, United Kingdom

We declare under our sole responsibility that

the medical **Product Name** WorkstationOne

device(s)

Type/model, identification n/a

of product allowing traceability (Where applicable)

according to rule 12, annex IX of of class

directive 93/42/EEC

is/are in conformity with the provisions and requirements of UK Medical Devices Regulations 2002 (UK SI 2002 No 618, as amended)

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Applied harmonised ISO 13485:2016 standards, national EN ISO 14971:2019 standards or other normative documents IEC 62304:2006

Conformity

assessment

MDD 93/42/EEC Annex V procedure

Approved Body n/a (name & number)

Signed on 14th of February 2024, at Carmel, CA, USA

Name of authorized signatory: Patrick Heffernan

Position held in the company: CEO & CTO