



# EU Declaration of Conformity



according to the Medical Devices Regulations 2017/745

**Manufacturer:** Three Palm Software

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

**SRN:** US-MF-000002924

**Authorised Representative:** Wellkang Ltd, Enterprise Hub, NW Business Complex,  
1 Beraghmore Rd, Derry, BT48 8SE, Northern Ireland, UK  
SRN: XI-AR-000001836

**We declare under our sole responsibility that**

<b>the medical device of class</b>	Product Name	:	WorkstationOne
	Type/model	:	n/a
	Basic UDI DI	:	++B148WSONE1939Y
	according to rule 13, Annex VIII	:	Class I

**is in conformity with the provisions and requirements of 2017/745.**

Applied harmonised standards, national standards or other normative documents	ISO 13485:2016
	ISO 14971:2019
	IEC 62304:2006
	IEC 62366-1:2015+AMD1:2020

Conformity assessment procedure      Chapters I and III of Annex IX

Notified Body (name & number)      n/a  
Certificate & number

Signed on 14<sup>th</sup> February 2024, at Carmel, CA, USA

Signature 

Name of authorized signatory: Patrick Heffernan  
Position held in the company: CEO & CTO