



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

We declare under our sole responsibility that

the medical device of class	Product Name	:	CadOne
	Type/model	:	n/a
	UDI DI	:	B148CADONE3260
	according to rule 13, Annex VIII	:	Class I

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

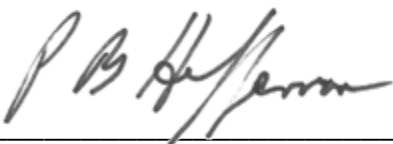
Applied harmonised standards, national standards or other normative documents	ISO 13485:2016	_____	_____
	EN ISO 14971:2012	_____	_____
	EN 62304:2006	_____	_____

Conformity assessment procedure: Chapters I and III of Annex IX

Notified Body (name & number): n/a

Certificate & number: _____

Signed on 14th of April 2021, at Carmel, CA, USA

Signature 

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