



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

the medical device of class	Product Name	:	CadOne
	Type/model	:	n/a
	Basic UDI DI	:	++B148CADONE3260VK
	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) Certificate & number: n/a

Signed on 26th of January 2026, at Carmel, CA, USA

Signature 

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