Doc No.: MY-EN-MDRCE
Rev No.: 1.2

EC DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017

Manufacturer name : SAS KINVENT BIOMECANIQUE
Manufacturer's address : Zac Eureka, Bâtiment Apollo A, 6 Rue de Pommessargues, 34000 Montpellier, France, Telephone: +33 411280695
Manufacturer's SRN : FR-MF-000031884

Name	Model	Basic UDI-DI	GMDN NAME	GMDN Code	UMDNS Code
K Myo	K Myo	3770011995KMyo95	Electromyograph	11474	11474
K Myo	K Myo, Black	3770011995KMyo95	Electromyograph	11474	11474

Intended Use : The K-Myo is intended to be used by trained professionals to assist with qualitative evaluating the muscle activity.
Device Class and Rule : Class I, Rules 1, 9 & 13 of Annex VIII of EU MDR 2017/745

We hereby under our sole responsibility declare that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and fulfils the general safety and performance requirements.

This declaration of conformity is issued under the sole responsibility of SAS KINVENT BIOMECANIQUE in compliance with Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified above meets the provision of the Annex IV of Regulation EU 2017/745 for medical devices.

This declaration is based on:

(A) Harmonized Standards

EN ISO 14971 :2019, EN ISO 10993-1:2020, EN ISO 15223-1 :2021 EN 60601-1:2006/A1:2013, EN 60601-111 :2015/A1 :2021, EN 60601-1-2:2021, EN 62304:2006/A1 :2015, EN ISO 13485:2016, EN ISO 20417:2021

(B) Technical File. ID Number: P-21e Medical Device File Myo_V1R1, issued on 25.09.2023

CE

Manufacturer : *SAS KINVENT BIOMECANIQUE*
Authorized Signatory & Designation : *Athanase Kollias, CEO*
Signature :

KINVENT
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DocuSigned by:
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Place : *Montpellier, France*
Date : *06/12/2024*