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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 : Cap omega - cs 39521, Rond-Point Benjamin Franklin
34000 Montpellier, France, Telephone: + 33 4 67 13 00 33
Manufacturer's SRN : FR-MF-000031884

Name	Model	Basic UDI-DI	GMDN NAME	GMDN Code	UMDNS Code
KForce Plates	K Force Plates	3770011995KPlatesD2	Biomechanical function analysis system, force-testing, portable	63456	17242
KForce Muscle Controller	K Push	3770011995KPushET	Back/leg/chest dynamometer, electronic	61672	17681
KForce Bubble	K Bubble	3770011995KBubble7M	Back/leg/chest dynamometer, electronic	61672	17681
KForce Grip	K Grip	3770011995KGripBX	Hand dynamometer / pinch meter, electronic	33785	17681
KForce Link	K Pull	3770011995KPullEE	Back/leg/chest dynamometer, electronic	61672	17681
KForce Sens	K Move	3770011995KMoveDB	Electronic goniometer/ kinesiology sensor	33652	13536
KForce Deltas	K Deltas	3770011995KDeltas7S	Biomechanical function analysis system, force-testing, portable	63456	17242
KForce Deltas	K Deltas XL	3770011995KDeltas7S	Biomechanical function analysis system, force-testing, portable	63456	17242

Intended Use : The K-Sensors are intended to be used by trained professionals to assist with objective assessment of a person's physical strength, balance, and range of motion.
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 60601-1-11 :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-21 Medical Device File_V1R6, Issued on 05.07.2023.

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

Signature :

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Place : Montpellier, France
Date : 26/10/2023